HUMAN
FERTILISATION
&
EMBRYOLOGY
AUTHORITY

HFEA

THIRD ANNUAL REPORT · 1994

Front Cover

Financial Times

8 January 1994.

This article was written by Clive Cookson about the HFEA and its public consultation document on donated ovarian tissue.

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HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY
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This report covers the year beginning 1 November 1992
with a forward look for the year beginning 1 November 1993

THIRD ANNUAL REPORT · 1994

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CONTENTS

INTRODUCTION 2

CHAIRMAN'S FOREWORD 4

1 STRUCTURE OF THE AUTHORITY

1.1 The Structure of the Human Ferilisation and Embryology Authority 8

2 CODE OF PRACTICE

2.1 Introduction 10

2.2 Parental Orders 10

2.3 Policy Decisions Made by the Authority 10

3 SOCIAL AND ETHICAL ISSUES

3.1 Embryo Freezing 14

3.2 Donated Ovarian Tissue Consultation Document 15

3.3 Oncology Patients 15

4 COMMUNICATIONS

4.1 HFEA's General Communications 18

4.2 Code of Practice on Enforcement 18

4.3 HFEA Conferences 18

4.4 British Fertility Society Survey 19

5 LICENSING

5.1 Licences Issued and Refused 22

5.2 Inspections 22

5.3 Breaches of the HFE Act and Code of Practice 22

5.4 Mid-term Monitoring and Review 23

5.5 GIFT Survey 23

5.6 Transport-IVF 23

6 DONATION OF GAMETES

6.1 Survey of Donors 26

7 RESEARCH

7.1 HFEA Remit 28

7.2 Approach to New Techniques 29

7.3 Future Issues 30

8 ISSUES FOR THE COMING YEAR

8.1 Forthcoming Issues 32

9 INCOME AND EXPENDITURE

9.1 HFEA Budget 36

9.2 Licence Fees 36

10 DATA COLLECTION

10.1 Introduction 38

10.2 IVF Tables: 1 Jan-31 Dec 1992 38

10.3 Donor Insemination Tables: 1 Jan-31 Dec 1992 42

ANNEXES:

1 Membership of the Human Fertilisation and Embryology Authority 45

2 Members of HFEA Committees and Working Groups 46

3 List of Centres Currently Licensed by the HFEA for Treatment 47

4 List of Current Research Projects 49

5 List of Current HFEA Inspectors 50

6 HFEA Accruals Accounts 1992/93 51

7 1992 HFEA IVF and DI Tables of Specialist Interest 52

8 Glossary of Terms 54

The Human Fertilisation & Embryology Act was passed by Parliament in 1990. The Act broke new ground in the relationship between medicine and the law. In August 1991, the Human Fertilisation and Embryology Authority took up its task of regulating research using human embryos, the storage of gametes and embryos and the use in treatment of donated gametes (eggs and sperm) and of embryos produced outside the human body.

As a regulatory body, much of the Authority's work relates to the inspection and licensing of centres carrying out *in vitro* fertilisation (IVF), donor insemination (DI) treatment or embryo research. The members of the Authority ensure that human embryos are used responsibly and that infertile patients are not exploited at a vulnerable time.

“We cannot stop the advance of science but we can decide how we want to limit its effects”

The Independent,
7 January 1994.
This article was written about the HFEA and its public consultation document on donated ovarian tissue. It was written by Celia Hall and titled “Who decides how babies are made”.

CHAIRMAN'S FOREWORD

We have now completed our third year of controlling aspects of assisted reproduction and embryo research. It has proved to be an active and exciting year for the Authority as we developed significantly as an organisation and confronted new challenges. In meeting new demands, we built on past experience and refined our approach to various issues affecting patients and centres.

Some people may wonder what we as an Authority do. They will be aware that the Authority was set up to regulate IVF and donor insemination centres and to ensure that reproductive technology does not get out of control. But how do we do that? This Annual Report gives an overview of the Authority's activities over a twelve month period.

Regulation

We stipulate and set standards for fertility centres and embryo research centres and license only those which meet our criteria. Our licensing programme stretches over the year and each centre is inspected by a team of our inspectors at least once in that period. This is time-consuming but vitally important work.

We also monitor new developments in treatment and consider their risks and benefits, the skills needed to carry them out and whether they are necessary or desirable. Over the past year one such new development, the technique known as Intra Cytoplasmic Sperm Injection (ICSI), has gained some prominence in the treatment of male infertility. This technique involves the injection of a single sperm directly into the egg. The Authority has licensed some centres to do ICSI but we remain of the view that the technique must be carefully monitored and that patients must be fully informed of the potential risks involved in using such a new technique.

Ethical Issues

In 1993 the Authority carried out a public consultation on the question of sex selection and decided that it was acceptable for medical reasons but not for social reasons.

We considered cloning by embryo splitting and concluded that we would not allow it either in treatment or in research leading to treatment. This year has brought another public consultation on issues relating to the possible uses of ovarian tissue from different sources.

Other issues which have gripped people's imagination and interest over the last few months concern whether there should be an upper age limit for fertility treatment; the use of eggs from caucasian donors for the treatment of women from ethnic groups; and treatment in exchange for egg donation. These are issues which we are reviewing, in working groups or as part of our regular Code of Practice review. The Authority also commissioned a survey of sperm donors so that we could have a more solid basis on which to make future decisions affecting sperm donation. Over the year we have also been studying embryo freezing and we will be producing a leaflet for patients on this subject.

Information

The Authority collects data from all the licensed centres about every IVF and donor insemination treatment and its outcome and about every donor. We are required by law to collect this information so that children born as a result of donation may come to us when they reach maturity to find out something about their genetic history. The data is stored on our computerised register, and thanks to the admirable efforts of centres and of the Authority register staff, the initial problems of obtaining consistent and validated information are steadily being overcome.

We have also made progress in improving our data collection and the information we can publish as a result. We are considering the feasibility of publishing success rates for individual centres. This is perhaps the most frequent request we get from patients who are about to choose a centre. However, producing success rates is not the straightforward task it might first appear. Success rates depend on a number of factors, including the age of the women being treated and the reasons for the infertility. A set of reference data which allows for valid comparisons between centres therefore needs to be identified. Our objective is to provide people with information which is both meaningful to them *and* fair to centres. We are determined to find a solution which is widely acceptable in the coming year.

Communications

There has been a marked increase in the national and international interest in the role and work of the Authority. Through this greater public profile, patients and others have become more aware of who we are and increasingly come to us for information. We try to be as open and helpful as possible in providing advice and information. We consider this to be an important part of our statutory responsibilities.

The demands on the Authority are growing but we welcome the interest and challenges that these bring. We recognise that we need to be accessible and informative about our own activities, the activities in the fields we regulate and the potential impact of new technologies. Increasing interest from the public and the media is welcomed. We need to have the confidence of the wider community to be successful in our task. We are greatly encouraged by the voluminous response we have had to our consultation on the use of donated ovarian tissue and we will look for other opportunities to involve people in our decision making.

Conclusion

During the last year some of our members retired from the Authority, having served their terms of office most ably since its inception. I am very grateful to them for their hard work and dedication in helping to build a firm foundation for the work ahead. Their contribution has been considerable. At the same time, I am pleased to welcome new members to the HFEA. Their fresh thinking and enthusiasm will add to the vigour of the Authority.

The Authority has expanded its role over the years and has shown itself to be fully effective in carrying out the responsibilities with which it was charged by Parliament. It has benefitted from the unstinting hard work of its members and staff, from members co-opted from outside and from the constructive feed-back it receives from centres and others. I wish to record my gratitude to them all for their help.

Colin M. Campbell

Professor Sir Colin Campbell
Chairman

&

“We come from many walks of life, including law, religion, counselling, nursing, training and the media”

Sunday Express,
6 March 1994.
This article, entitled “Where do we draw the line on embryos?”, was written by the Chairman of the Authority. It covered the topical issues in the media about fertility treatment and the HFEA’s document consulting the public on donated ovarian tissue.

CTION 1:

RUCTURE OF THE AUTHORITY

1 THE STRUCTURE OF THE UMAN FERTILISATION AND MBRYOLOGY AUTHORITY

he Authority consists of 21 members, cluding its Chairman and Deputy Chairman, ho are appointed by the Secretary of State for ealth. It is a requirement of the Human ertilisation and Embryology Act 1990 that oth the Chairman and the Deputy Chairman well as at least half of the membership are ot involved in medical or scientific practice. hey represent a broad range of views and xperience, medical, scientific, social, legal, lay nd religious. They determine licence pplications and decide policy.

Most Authority members are involved in official Authority business about three times each month. They attend monthly meetings where agenda items are discussed by the entire Authority. Members also attend various inspections, licence committees and other standing committee or working group meetings.

Members of the Authority

A full list of the Authority members is at Annex 1 nd membership of each committee and working group is at Annex 2.

The Executive of the HFEA has been eorganised during the past year, creating a new structure for the 22 members of staff which will allow the Executive to meet the Authority's objectives more efficiently and effectively. Broadly, the Executive's work is divided into two areas: policy, communications and resources and licensing enforcement and the information register.

Flora Goldhill
Chief Executive

Hugh Whittall
Deputy Chief Executive

> “While there has been public clamour in recent weeks. . . . the Authority has been calmly getting on with it for three years”

***The Independent*,**
7 January 1994.
This article was written about the HFEA and its public consultation document on donated ovarian tissue. It was written by Celia Hall and titled “Who decides how babies are made”.

The Code of Practice is a 46-page document produced by the HFEA and given to each licensed centre and is freely available to the public. This Code, which forms the backbone of the Authority’s work, sets the standards – professional, ethical and legal – that centres should adopt. There are 11 sections of the Code of Practice. These include guidelines on what is expected of the different personnel working in centres, guidance on how to assess the welfare of the child and the information that must be given to potential patients and donors.

The Code seeks to protect the interests of infertile people, the donors and the resulting children. It is revised regularly to ensure that it continues to promote the best possible practice.

CODE OF PRACTICE

2.1 INTRODUCTION

The Code of Practice was last revised in July 1993. A number of policy decisions have been made during the past year, however, and these will be incorporated into the next revised edition. The Authority agreed that it would be sensible to produce this edition of the Code of Practice after the regulations under section 30 of the Human Fertilisation and Embryology Act 1990 (HFE Act) had been made. This will allow guidance on the regulations, which introduce parental orders, to be included. In the meantime, important decisions are notified to centres as they arise (see para 2.3). The Authority will keep licensed centres up-to-date with other policy matters by means of six-monthly letters to Directors of centres. The first of these was sent in February 1994.

2.2 PARENTAL ORDERS

Section 30 of the HFE Act is the last remaining major section to be given effect. It will bring into being new legal instruments called parental orders. In the case of the birth of a child to a surrogate mother, parental orders will allow the transfer of legal parental responsibility to the commissioning parents from the surrogate parents without the need for full adoption procedures. The Government is finalising the regulations to introduce parental orders and draft guidelines explaining their implications are being considered by the HFEA Code of Practice Committee. The revised Code of Practice will give guidance about the role of licensed centres in applications for parental orders. It will also explain what will need to be stated on the birth certificate when a birth to surrogate parents is registered – a matter which has caused some confusion in the past.

2.3 POLICY DECISIONS MADE BY THE AUTHORITY

The following policy decisions have been made and notified to centres by the Authority during the year:

Sex Selection

In January 1993 the Authority launched a public consultation on the issues surrounding the use of sex selection techniques in assisted conception. Over 2000 copies of the consultation document were distributed and approximately 200 responses were received from centres, infertile people, women's groups, religious groups, ethnic organisations and others. The Government asked the Authority to inform it of the outcome and of any decision reached following the consultation.

A range of arguments for and against the use of assisted conception techniques to select the sex of children for *social reasons* was set out in the consultation document. No additional arguments were put forward during the consultation period. The Authority was persuaded by the balance of arguments set out in the document against the use of sex selection for social reasons.

The Authority approved in principle the use of sex selection techniques for *medical reasons* in cases where a woman risks having a child with a life-threatening, sex-linked disease. The Authority already licenses one IVF centre for the use of this technique as part of its IVF programme. However, the Authority has decided that the data currently available on the success of primary (ie pre-fertilisation) techniques like sperm sorting do not support the use of these methods for medical reasons at this time.

Ministers and licensed centres were notified of the Authority's decisions in letters from the Chairman in July 1993. These detailed the Authority's decision not to permit sex selection techniques for social reasons, allowing it for medical reasons alone and only where secondary techniques (ie post-fertilisation) are used.

Cloning

One method of cloning an embryo (by replacing a nucleus) is forbidden by the Human Fertilisation and Embryology Act 1990. Although cloning by splitting embryos is not prohibited by the law, it may not be carried out without a licence from the HFEA. Last year the Authority considered the social and ethical implications of cloning. The HFEA has decided not to license the use of cloning by splitting embryos for treatment, nor for research directed towards the development of cloning for treatment. This decision does not affect the licensing of embryo biopsy where there is no intention to develop removed cells into embryos for replacement in the womb.

Using stored embryos produced from donors who have produced 10 children

Last year several centres reported to the Authority cases of couples wishing to use for themselves, or to donate for the treatment of others, embryos which had been in storage for some time. These embryos had been produced using the eggs of the female partners and the sperm of donors who were now known to have fathered 10 children. The centres were uncertain how to advise the couples since the Code of Practice makes it clear that "donated gametes or embryos should not normally be used for treatment once the number of live children born as a result of donations from that donor has reached 10" (para 7.18).

The Authority has decided that, provided the stored embryos were produced *in good faith at a time when the donor was not known to have produced 10 offspring*, they may be considered an allowable exception to the Code of Practice limit. As always, the Authority should be notified whenever the limit of 10 is exceeded. It should be clearly understood that this does not represent a general relaxation of the limit of 10 offspring per donor. The Authority will be monitoring the situation to establish whether the limit of 10 children is being frequently exceeded.

Using donors of a different ethnic origin from recipients

There have been several cases recently reported in the press involving treatment for black or Asian women with eggs donated by white women. One black Italian woman, married to a white man, wished to receive the eggs of a white woman for social reasons. Another woman, in the UK, whose husband was of mixed race, was offered treatment using the eggs of a white donor since no eggs from a black donor were available.

The Code of Practice says that centres should "take into account each prospective parent's preferences in relation to the general physical characteristics of the donor which can be matched *according to good clinical practice*" (para 3.20). Matching of donors with recipients should be carried out sensitively in discussion with those seeking treatment and the centre. The HFEA recognises that a shortage of donors, particularly of donors from ethnic groups, may constrain the choice available in some cases. However, the Authority would not regard it as good clinical practice if a licensed centre allowed a woman's preference for a child of different ethnic origin from herself to determine the choice of an egg donor. Similarly, a woman seeking donor insemination should not be allowed to choose for social reasons a sperm donor from an ethnic group different from that of her partner.

Treatment of older women

It was mentioned in the last HFEA Annual Report that the Authority would be considering the issue of whether older, particularly post-menopausal, women should be given fertility treatment.

It continues to be the view of the Authority that it is neither necessary nor advisable to fix an upper age limit for the treatment of infertility. Licensed centres are required by law to consider the welfare of the prospective child. The Code of Practice says that in doing so they should take account, amongst other things, of the age and medical history of the prospective parents and of their ability to meet the child's needs. The Authority believes that each case should be considered individually, bearing in mind the welfare of the child and all the implications for the couple concerned.

Since the Authority began collecting IVF data in August 1991, only a small number of women over 50 years old have been treated and several of these used their own eggs. The Authority would be concerned if a centre were repeatedly treating older women and would require such a centre to justify this practice in terms of the welfare of the child. The Authority is keeping the situation under constant review.

“Even before the researchers have devised a technique, the Authority has initiated a debate”

The Guardian,
8 January 1994.
An editorial comment entitled “Applying the science for a fertile debate” raised issues surrounding the launch of the HFEA’s public consultation document on donated ovarian tissue.

The policy making of the Authority is divided between its committees and its working groups: a Licensing and Fees Committee, a Code of Practice Committee and ad hoc working groups on social and ethical issues and information. These working groups and committees consider policy matters in detail before bringing their recommendations to the full Authority.

In reaching its conclusions, the Authority has two particular concerns: that people seeking treatment and donors should receive the highest possible standards of service and that the interests of all those involved are recognised by an informed analysis of the issues.

SECTION 3:

SOCIAL AND ETHICAL ISSUES

3.1 EMBRYO FREEZING

The Authority decided last year to change the way in which it considers social and ethical issues. The standing Committee on Social and Ethical Issues was replaced by ad hoc working groups of members and relevant experts from outside the Authority to investigate and report on particular topics. The first topic to be examined was embryo freezing and its implications for patients, for treatment centres and for research. The Working Group on Embryo Freezing was then set up.

The HFEA Code of Practice states that no more than three embryos can be transferred in an IVF treatment cycle. However, IVF treatment commonly involves drug stimulation of the woman's ovaries to produce more than three eggs. The "spare" eggs can be fertilised *in vitro* and frozen-stored for the woman's use in a future treatment cycle. When a centre has no freezing facilities, one of the options is to use the spare embryos, with the couple's consent, for research. An important question for the Working Group and HFEA was whether it was appropriate for centres to offer IVF treatment where there was no opportunity for spare embryos to be stored for the patients' future use. Another issue considered by the Working Group was whether there might be a need to extend the maximum storage period for embryos beyond the present statutory five year limit.

The Working Group investigated which centres were offering embryo freezing services, the methods of freezing used, the experience and views of centres and of patients, the information available on the likelihood of achieving pregnancy from frozen embryo transfers and the cost and consequences for research of the availability of embryo freezing.

The Working Group reported that almost all licensed centres now either make embryo freezing available to patients or expect to do so before very long. No evidence was found of lack of safety for patients or their potential children in the use of frozen embryos in treatment. The Group also found that many centres offering frozen embryo replacement were able to obtain embryos for research, so freezing and research were not incompatible. The Working Group's investigations also identified a lack of consistent, objective information for patients on the implications of embryo freezing.

The Authority agreed not to insist that all IVF centres should offer embryo freezing themselves. However, it is concerned that patients should be given all the information they need to make properly informed decisions about whether to have their spare embryos frozen-stored. The Authority has therefore decided to publish a leaflet for patients about the implications of embryo freezing. The Authority also believes that long-term results of frozen embryo transfer should be studied.

The maximum storage period of five years for embryos in storage at 1 August 1991 (when the Authority took up its powers) expires on 31 July 1996. The Authority believes that more needs to be known about the views of patients on the maximum storage period for embryos and a survey into this is planned for the coming year. In the meantime, discussions will be held with the Department of Health about the implications of changing the five-year period.

3.2 DONATED OVARIAN TISSUE CONSULTATION DOCUMENT

Notice was given in last year's Annual Report of the Authority's intention to consult the public on the complex issues surrounding the possible use of donated ovarian tissue, including fetal tissue, in embryo research and treatment. The techniques needed to use this tissue in research or treatment are still at the early stages of development. It will be some years before fetal material or grafted ovarian tissue from other sources could be used to produce human embryos. However, the Authority considered it right to have wide public debate on the issues before scientific development reached the stage where decisions would be needed.

Members of the Executive

On 7 January 1994 the Authority published its public consultation document entitled "Donated Ovarian Tissue in Embryo Research and Assisted Conception". The document explained why human eggs and ovarian tissue are needed and the possible benefits to embryo research and treatment. It identified many of the issues to be considered before the HFEA made any decisions about whether research or treatment using this tissue should proceed. These included concerns about the physical and psychological welfare of offspring who might be produced and issues of consent. The document invited views on using donated ovarian tissue, in research or treatment, from three different sources: live donors, donors who had died and aborted fetuses. The Government asked the Authority for advice on what, if any, action needed to be taken following the consultation.

The consultation aroused great interest in the media, Parliament and amongst the general public. 23,000 copies of the document were distributed to interested organisations and to individuals on request. There was also considerable interest in the document from abroad. As a result of this wide interest, the consultation period was extended from 1 June to 15 July 1994.

At the time of writing, the Authority is considering the responses received. The Authority plans to report its decisions in the Summer.

One of the consequences of this consultation has been a marked increase in national and international awareness of the role and work of the Authority.

Another particular consequence has been that an amendment to the Criminal Justice and Public Order Bill was put forward which would ban the use of fetal eggs, or embryos derived from fetal eggs, in fertility treatment. The Bill has not yet passed through both Houses of Parliament so the final outcome on this issue is not known.

3.3 ONCOLOGY PATIENTS

A significant number of centres store sperm from men about to undergo treatment for cancer, for their own possible use in the future, should the treatment impair their fertility. The Authority has agreed to give consideration to the way in which the centres' legal obligations to offer suitable counselling and provide relevant information should be interpreted in such cases. Questions arise about whether it is appropriate for patients, who are often in their teens or early twenties, to be offered counselling about their future fertility when treatment for cancer is about to commence. In addition, Schedule 3 of the HFE Act requires that people give effective consent before their gametes are stored, including consent to its use or disposal after their death. Seeking and obtaining this consent may present difficulties. This problem will be addressed in the coming year.

> "We are committed to ensuring patients have good information"

The Times,
17 January 1994.
This article was by Jeremy Laurance, entitled "Move to monitor fertility clinics' success". Deputy Chief Executive Hugh Whittall was quoted in this article which considered the possibility of publishing comparative success rates.

The Authority has been increasingly involved in communicating with the public about its work. For all those interested in fertility treatment, an extensive information package is available. This includes the HFEA's Annual Report, a list of licensed centres and the following leaflets:

"The Role of the HFEA"

"Sperm and Egg Donors and the Law"

"In Vitro Fertilisation"

"Egg Donation"

"Treatment Clinics: Questions to Ask"

and the RCOG's

"Donor Insemination".

Also available are two videos (for patients attending centres and educational purposes only), the Code of Practice, consultation documents and the Code of Practice on Enforcement.

COMMUNICATIONS

4.1 HFEA'S GENERAL COMMUNICATIONS

Over the last year the public profile of the Authority has risen considerably. Interest in the Authority's work has come from regional, national and international sources, with numerous requests for information, interviews, articles and talks. Enquiries from international television and radio stations have also increased as more countries look to the Authority as a possible model for regulation. The Authority has cooperated fully in order to inform the public about its work.

During the past year consideration has therefore been given to the educational role of the Authority in providing information and encouraging informed debate. The Authority has briefed journalists to help develop their understanding of assisted reproduction and the Authority's role. Media attention has increased the public's awareness of the Authority's work and this has led to a large number of enquiries. In addition, members of the Authority and the Executive have been invited to attend, and speak to, various conferences, schools, meetings of medical organisations and religious and other groups. Since the launch of the consultation document on donated ovarian tissue, the Authority itself has held five public meetings across the country where members of the public have been invited to give their views on this contentious topic.

4.2 CODE OF PRACTICE ON ENFORCEMENT

In July 1993 the Prime Minister, with the support of the Department of Trade and Industry, published a leaflet stating that all government enforcement agencies would adopt a Code bringing together deregulation and Citizen Charter principles. Such principles would be assured through the publication by each agency of its standards and procedures for dealing with clients and particularly how complaints would be handled. The Code's aim is to benefit organisations and individuals by minimising the cost of complying with regulations and to ensure that regulations achieve their objectives. The leaflet listed all government enforcement agencies to be covered by the Code and included the HFEA.

The HFEA's Code of Practice on Enforcement is based on its commitment to deal with any requests or complaints promptly and to ensure that it keeps its administrative costs to a minimum. The Executive endeavours to answer all queries from the public, press or licensed centres as promptly as possible. There is a 24 hour answering machine service, linked to a pager service, allowing urgent phone calls to be dealt with outside office hours, including weekends and bank holidays.

Copies of the HFEA's Code of Practice on Enforcement are available free of charge from the Authority.

4.3 HFEA CONFERENCES

During the period November 1992 to November 1993 the HFEA organised four conferences. In February 1993 the HFEA facilitated a conference which brought together individuals and organisations with an interest in training for infertility counsellors. The outcome of the conference was the establishment of a working group to examine training for people providing infertility counselling. This Working Group on Training in Infertility Counselling met for the first time in May 1993 and has now produced a report for the Authority on the way forward.

Another conference was held for HFEA Inspectors focusing on feedback from questionnaires sent to them, asking for their views on, and experiences with, HFEA inspections. A particular focus of the conference was the assessment of a centre's compliance with the requirement to consider the welfare of the child. A third gathering was held in June 1993 on the licensing of new techniques, focusing on the introduction of the micromanipulation technique Intra Cytoplasmic Sperm Injection (ICSI) into licensed treatment practice.

The HFEA Annual Conference was held in July 1993. Over 200 delegates, mostly from licensed centres, participated in a full day of talks on the theme of "Setting Standards in Regulated Fertility Treatment". Ideas were exchanged with representatives from licensed centres and other interested bodies. Speakers included Dr Howard Jones, a guest speaker from America, who spoke about attempts to regulate IVF treatment in the USA; Mr Andy Walker of the Association of Clinical Embryologists spoke of the progress in developing professional standards in embryology; Dr Elizabeth Lenton spoke about performance indicators in clinical practices; Ms Jennifer Hunt focused on the benefits to patients of providing trained infertility counsellors; and a former fertility patient spoke of her own experiences with IVF.

4.4 BRITISH FERTILITY SOCIETY SURVEY

Between January and October 1993 the British Fertility Society (BFS) conducted an independent survey of licensed fertility treatment and storage centres. The survey was the first to assess the anonymous opinions of the "persons responsible" in each licensed centre regarding the administration of the Human Fertilisation and Embryology Act 1990 and its impact on clinical medicine. It provided an opportunity both to voice criticism and to suggest practical improvements in the inspection and licensing system. The results represented the views of 80% of the "persons responsible".

The majority of respondents felt that the Code of Practice was working well, though some believed that the emphasis on counselling, particularly at annual inspections, was disproportionate when compared to clinical and laboratory matters. Some respondents thought that a more flexible approach in certain patient groups could be adopted by varying the number of embryos replaced to two in younger women and to four in older women (the maximum is three as stated in the Code of Practice). These findings indicated continuing anxiety with the relatively high incidence of multiple pregnancies in women receiving IVF and the reduced probability of pregnancy in those over the age of forty.

The results of this survey were presented to the Authority and this information will be used to help improve the administration of the HFE Act and the work of the HFEA.

The BFS survey is fully documented in an article by Dr B Lieberman, Dr P Matson and Dr F Hamer titled "The Human Fertilisation and Embryology Act 1990: How well is it functioning?" in *Human Reproduction*, volume 9, issue 9 (in press).

&

“The HFEA has statutory powers and is prepared to use them”

Daily Express,
7 January 1994.
This article was written by Diana Brittan, Deputy Chairman of the Authority. The article, titled “Donor eggs: the moral dilemma”, covered a number of ethical issues the Authority had become involved in after Christmas, foremost the debate surrounding the use of donated ovarian tissue.

A licence is requir for certain specific activities:

- IVF treatment and any fertility treatment involvin donated human eggs or sperm;
- storage of human eggs, sperm or embryos for treatment or for research; and
- embryo research

When an application for a licence is received from a centre, an inspection is arranged. The inspection team usually consists of four people with relevant expertise, at least one of whom will be a member or employee of the Authority. They will then report to a licence committee which is made up of Authority members. This licence committee will decide whether or not to grant a licence and with what specific conditions, if any.

SECTION 5:

LICENSING

5.1 LICENCES ISSUED AND REFUSED

The HFEA currently licences 67 centres for IVF treatment and another 37 for donor nsemination only. A list of licensed centres is at Annex 3. There are currently 9 centres which are licensed only for the storage of sperm and 39 licensed research projects. A more detailed report on research is provided at Section 7.

Seven new IVF licences have been issued during the year. By definition, a newly licensed centre will not, at the time the licence is issued, have carried out any licensable treatment. As with all centres, the Authority will monitor these centres to ensure that their practice meets the standards required by the HFE Act and the Code of Practice.

During the year a licence committee proposed not to renew the licence of one IVF centre and to revoke the licence of an associated centre. This matter is the subject of licence committee proceedings. A further treatment licence was suspended. This licence subsequently expired and no renewal was sought. Four research applications were refused during this period.

5.2 INSPECTIONS

The Authority normally inspects each licensed centre every year. It is a legal requirement that this should be carried out, except that the Authority may omit an inspection in a particular year if there are specific reasons for doing so.

In the first two years of the Authority's existence inspections enabled it to become familiar with individual centres and to develop a detailed knowledge of their working practices and procedures. As the Authority moved into its third year of inspections and licensing, there was a change in the way inspections operate. Whereas on earlier visits inspectors would cover all issues referred to in the HFE Act and Code of Practice, they now increasingly concentrate on issues of particular significance in each centre. A list of HFEA inspectors is at Annex 5.

This new approach is not primarily intended to review centres' previous failings or to identify new ones, though this may happen. It should enable the Authority and inspection teams to advise in greater detail on good practice and to enable the centres to show examples of good practice which the Authority can disseminate elsewhere. It is very much hoped that this will be part of a constructive dialogue which will help improve standards and results throughout licensed centres. Centres are aware of the Authority's powers to examine premises, practices and records and to take any necessary action.

Members of the Executive

5.3 BREACHES OF THE HFE ACT AND CODE OF PRACTICE

The Authority has investigated a number of alleged breaches of the HFE Act or of the Code of Practice. In such cases, the Authority makes preliminary enquiries to establish whether there is *prima facie* evidence of a breach. If there is such evidence, the Authority investigates the facts and circumstances of the alleged breach and takes specialist, including legal, advice where necessary.

Once sufficient information has been obtained, this will be referred to a licence committee which will decide what further action, if any, needs to be taken. Where there is a possibility that a criminal offence may have been committed, the committee will decide whether the matter should be referred to the Director of Public Prosecutions.

Significant breaches, including, for instance, the import of sperm without a special direction or the use of sperm from an unregistered donor, have been dealt with through additional licence conditions and subsequent close monitoring.

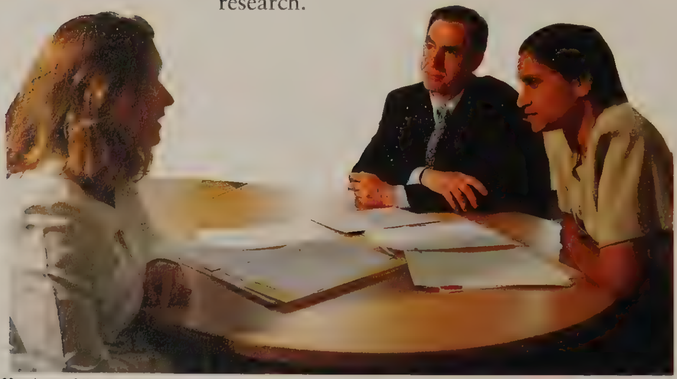
Licence committees insist on the maintenance of the highest standards. Any breach of the HFE Act or the Code of Practice could result in a licence being suspended or revoked.

5.4 MID-TERM MONITORING AND REVIEW

The Authority has recruited additional staff during the year to deal with the pressure of licensing. It is intended that more work should be done outside the programme of inspection visits (in partnership with centres) on improving areas that have been identified as causes for concern. In talking to centres about the positive aspects of their work, good practice can be shared with other centres, with the Authority acting as a conduit.

The Authority recognises that good and improving practice is mostly generated in the centres themselves. It is therefore important that the HFEA listens to the views of centres so that it can speak with authority when it discovers circumstances or practices that are less than ideal.

The overall aim will continue to be that of enabling centres to achieve and maintain the highest possible standards in treatment and research.



Members of the Executive

5.5 GIFT SURVEY

Gamete Intra-fallopian Transfer (GIFT) involves collecting eggs and sperm and placing them together into a woman's fallopian tube(s), usually by laparoscopy. GIFT can be appropriate treatment for couples with unexplained infertility, where the man's semen analysis falls within the normal range and the woman has at least one open and healthy fallopian tube. GIFT using the gametes of the couple concerned is not regulated under the HFE Act because it does not involve the creation of an embryo outside the body. It falls under the licensing system only if donated eggs or sperm are used. The one restriction the Authority places on GIFT is, as stated in the Code of Practice, that only three eggs can be transferred to a woman in one treatment cycle.

The Authority has sent a questionnaire on GIFT to all NHS consultants registered with the Royal College of Obstetricians and Gynaecologists. Replies to the questionnaire, which are expected by the summer of 1994, will enable the Authority to consider the implications of GIFT treatment for patients in both licensed and unlicensed centres.

5.6 TRANSPORT–IVF

Some guidance to licensed centres on the provision of transport-IVF, where preparation for treatment and egg collection are carried out at a satellite unit, was given in the 1993 revision of the Code of Practice. Since that time, the Authority has become concerned about the expansion of this form of treatment provision and has undertaken a review of the methods currently used in transport-IVF services. The Authority has decided that it will be necessary to inspect satellite centres in order to assure itself that the standards set out in the HFE Act and the Code of Practice, for all aspects of the treatment services provided, are consistently applied to both central and satellite units.

“About 3,000 couples seek donor insemination each year in the UK”

***The Times*, 8 January 1994. Letter to the Editor of *The Times* from Professor Ian Cooke (a member of the Authority) and Dr Sheila Cooke.**

There are currently over 1500 sperm donors and over 1000 egg donors registered with the Authority. This means that since August 1991, when the Authority took up its statutory powers, over 2500 people have donated their gametes at least once. In 1992 there were over 4000 couples who had received donor insemination.

The survey of donors commissioned last year by the Authority was enlightening in terms of the motivations of semen donors. Some women were polled regarding their attitudes to egg donation. The Authority has recently established a working group to consider issues relating to payment of donors.

DONATION OF GAMETES

6.1 SURVEY OF DONORS

Last year the HFEA commissioned a survey looking into the motivations and attitudes of semen donors. This was carried out by Professor Susan Golombok and Dr Rachel Cook of the Psychology Department at City University, London. Questionnaires were completed by 144 potential sperm donors attending 14 centres throughout the UK for screening between 1 November 1993 and 31 January 1994. A control group of 136 male students who had never donated sperm was recruited from City University and King's College Medical School. The students at City University were of all ages, attending part-time day and evening business courses.

Donors reported that both a wish to help others and the payment offered influenced their decision to donate. All of the donors believed that they should be paid and 62% reported that they would not donate sperm if not paid. One third of non-donors had considered donating sperm, the majority of whom (71%) had been motivated by the payment. For non-donors who had considered donating sperm but had never done so, the main reason for not going ahead seems to have been lack of motivation rather than serious concerns about the procedure or its implications.

Donors and non-donors were also asked about personal and social aspects of donating sperm. For donors, the most common concern was that they would be contacted by offspring produced using their sperm or that changes in the law would result in these offspring being able to identify them. Around 20% of donors also expressed concern about how they might feel about possible offspring in the future, how a current or future partner or wife might feel, how a future child of their own might feel and how their parents (ie the grandparents of any offspring) might feel if they knew. Compared with donors, non-donors were significantly more concerned about their future feelings towards any offspring and about how a future child of their own might feel.

Although the law does not allow men who donate sperm anonymously to receive information about any offspring, the respondents were asked whether they would wish to have such information if this were legally possible. Half of the donors (48%) would wish to know whether any children had been born as a result of their donation and a small proportion (15%) expressed a wish to meet any children when they reached 18 years of age. Donors were also asked how much information they would prefer any offspring to be given about themselves (the law permitting). Only 8% believed that identifying information about the donor should be given to the child, whilst almost two-thirds of donors (63%) stated that they would not donate sperm if the law allowed identifying information to be given to offspring when they reached 18 years of age.

The attitudes of 135 women students towards egg donation were also examined. Whereas over 90% were aware of the possibility of donating eggs, only 10% had ever considered doing so, almost all of whom were motivated by a wish to help others rather than payment. The women were more concerned than their male counterparts about the existence of children whom they would never know.

> “The roots of many diseases and disabilities begin before birth and we must not discourage this research”

Scotland on Sunday, 9 January 1994. This article, by William Paul, is based on an interview with Dr Roger Gosden about the potential use of donated ovarian tissue. It was titled “Of moral uncertainty”.

Research is a vital aspect of fertility treatment as further knowledge of embryology, the implantation of the embryo and the growth of the fetus may all have bearing on future methods of treatment. Scientific progress however can move very fast and the statutory controls must be able to keep up. The Authority investigates carefully all applications for research licences and does not permit any research that does not conform with the HFE Act.

SECTION 7:

RESEARCH

7.1 HFEA REMIT

Early knowledge of human embryology was based entirely on the physical description of embryos at different stages of development and comparison with processes in other species, mainly mouse. The first successful *in vitro* fertilization of mouse ova was achieved in 1959; human IVF followed ten years later. With the ability to freeze and store embryos, the possibilities for research on embryos have risen significantly in the past few years.

Research is vital for the advancement of clinical medicine. However, the public needs to be informed of advances of science, especially where research is being done on human embryos, given their special status.

All research on human embryos in the UK requires a licence from the HFEA. The procedure for considering research licence applications is broadly similar to that for treatment licences. Centres are inspected and are assessed on how they meet the requirements of the HFE Act and Code of Practice. Issues of consent, information for donors, security and the disposal of embryos are all relevant.

In addition, however, proposed research projects have to be approved by a properly constituted ethics committee at the hospital or laboratory where the research is to be performed and all projects submitted to the Authority are refereed by at least two independent experts. The Authority must be fully satisfied that the use of human embryos is essential for the purpose of the research before it grants a licence. It is only after these processes that the HFEA will consider issuing a licence. The Authority requires reports on the progress of the project and may discuss these during the course of inspections.

There are currently 39 licensed research projects. A list of these is at Annex 4. The projects can be classified into four research areas: congenital diseases (1), genetic abnormalities (8), general infertility problems (28) and miscarriage (2). Research on infertility includes projects investigating the maturation of embryos as well as factors affecting their implantation. Some projects fall within more than one category.

An area in which considerable advances have been made recently is in the diagnosis of genetic defects. It is estimated that 21,000 children are born each year in the UK with a significant genetic defect such as cystic fibrosis, haemophilia, Huntington's chorea and many others. Research licensed by the HFEA has progressed to the stage where there is a real hope that couples known to be at risk of passing on such conditions will soon be able to embark on a pregnancy confident that any resulting child will not be affected. It is now possible to take safely a single cell from an eight cell embryo (ie 2-3 days after fertilisation) and determine whether specific defective genes are present. It is then possible to transfer to the woman embryos which are unaffected.

The first single gene defect to be tackled in this way was cystic fibrosis by a group at the Hammersmith Hospital. Subsequently, these researchers have extended the approach to Lesch-Nyhan disease and other international researchers have used strategies based on the British research to reduce the likelihood of Tay-Sachs disease and Duchenne's muscular dystrophy. In principle any single gene defect might eventually be tackled in this way.

When debating the Human Fertilisation and Embryology Bill in 1989, Parliament considered whether *any* research on human embryos should be allowed. On a free vote, both Houses of Parliament decided that such research should in fact be permitted, albeit strictly controlled. This decision was incorporated in the HFE Act 1990 which states that no one can keep a developing embryo for longer than 14 days or after the appearance of the primitive streak (which is when the cells which are to form the fetus separate from those which are to form the placenta and umbilical cord). All research on human embryos must be licensed by the Authority and it may grant a licence only if the proposed research is *necessary* or *desirable* for at least one of the following purposes:

- to promote advances in the treatment of infertility;
- to increase knowledge about the causes of congenital disease;
- to increase knowledge about the causes of miscarriages;
- to develop more effective techniques of contraception;
- to develop methods for detecting the presence of gene or chromosome abnormalities in embryos before implantation.

Parliament decided that certain types of research on human embryos should be banned. It is illegal under the HFE Act to:

- place a human embryo in an animal;
- replace the nucleus of a cell of an embryo with a nucleus taken from elsewhere;
- alter the genetic structure of any cell while it forms part of an embryo.

7.2 APPROACH TO NEW TECHNIQUES

i) ICSI

In September 1993 the Authority issued guidance, "Developing and introducing new techniques, including intracytoplasmic sperm injection (ICSI)", to advise centres how best to introduce new clinical techniques into treatment programmes. It was recognised that there is a difficulty for centres wanting to use a new technique in clinical practice where, by definition, they are not able to show experience in carrying out that particular technique.

The Authority expressed the view that while a technique is still novel, centres should normally undertake a period of research which would add to the body of knowledge, but which would also enable the centre to demonstrate technical competence. Only after competence had been demonstrated would the Authority allow the centre to implement a treatment programme with the new technique. It was nevertheless acknowledged that there may be other ways, not involving research, of showing such competence. It would be for the centre to submit information to a licence committee on how this had been achieved.

ii) Ovarian tissue

The Authority has the responsibility to decide whether new techniques affecting the fertilisation of eggs *in vitro* should be introduced. If the Authority decides not to license an activity, then research scientists and clinicians cannot proceed.

During the past year the Authority has considered the development of certain techniques involving ovarian tissue, including that from cadavers or fetuses. These practices do not themselves require a licence, but could in the future impact on areas which are licensable. While research on the maturation of eggs can be carried out without a licence, the use of eggs for embryo research in IVF or GIFT require a licence. Scientists wishing to undertake research into the use of donated ovarian tissue from live donors, cadavers and fetuses have recognised the difficulties involved and are unwilling to proceed in this work until the Authority has concluded whether or not it will license IVF using material from these sources.

At the moment, freezing of ovarian tissue is taking place experimentally with the express purpose of protecting the reproductive capacity of young female cancer patients. However, the feasibility of grafting the tissue back into a woman is still unproven, though this has been achieved in animals.

In order to help and inform its decision-making, the Authority prepared a public consultation document about donated ovarian tissue which was issued in January 1994. When it has carefully considered the responses to this document, the Authority will make known its decisions on licensing.

7.3 FUTURE ISSUES

The HFEA takes seriously its role in monitoring research in the field of reproductive technologies. As scientific knowledge increases rapidly, developments in techniques such as the freezing of eggs and ovaries, co-culture of embryos and the *in vitro* maturation of eggs need to be closely monitored. During the coming year the Authority will monitor research aimed at identifying genetic causes of disease, as this is likely to have implications for preimplantation diagnosis (see section 8).

The Authority will continue to take steps to improve its monitoring of research developments in relevant fields and to extend its working contacts with the wider scientific community.

“New developments and new ethical issues will have to be confronted in coming years”

***Sunday Express*,**
6 March 1994.
This article, entitled “Where do we draw the line on embryos?”, was written by the Chairman of the Authority. It covered the topical issues in the media about fertility treatment and the HFEA’s document consulting the public on donated ovarian tissue.

Undoubtedly there will be concerns with new developments in fertility treatment and research. The Authority will endeavour to turn ethical issues which arise into practical applications. The Code of Practice will be amended accordingly.

SECTION 8:

SSUES FOR THE COMING YEAR

8.1 FORTHCOMING ISSUES

The Authority anticipates that the following ssues will need attention in the coming year:

Pre-implantation Diagnosis: Pre-implantation diagnosis entails the removal of one or two cells of an early embryo for genetic analysis. It is possible to establish the sex of the embryo and thus avoid genetic diseases which affect only boys or girls. Research is continuing on identifying whether or not a particular embryo is affected, unaffected or a carrier of a disease for which the parents are known carriers. Those which do not carry affected genes are chosen for transfer. This technique is clinically available in one HFEA licensed centre at present. The Authority will be consulting experts in the field to look at the way forward on pre-implantation diagnosis. Issues relating to diagnosis of different diseases will need to be addressed and consideration given to the preparatory work which centres will need to do before the technique can be introduced more widely in clinical practice.

Oocyte freezing: At the moment the freezing of eggs (oocytes) is at the developmental stage. Progress on egg freezing and its implications as an option for patients will be a matter for the attention of the Authority.

Monitoring: Inspections, which provide a snapshot view of practice at centres, have been the Authority's main method of monitoring centres. However, the Authority will be developing other methods to improve understanding of current developments. Closer monitoring through the HFEA information register, patient surveys and an assessment of complaints made both to centres and to the Authority will together provide a more complete picture of the way licensed centres are operating.

Academic studies: The Authority will be reviewing the role it takes in national and international studies, such as follow-up studies of the physical and psychological development of children born through assisted conception treatment. To date there has been little work done in this field. The HFEA is unable to play a direct role because of the confidentiality provisions of the HFE Act, but it will be looking at ways of encouraging long-term research by others. Research on the psychological effects on patients is another area where the Authority will be seeking to promote study (this may include the stress of multiple pregnancy and birth). The cost of treatment in terms of psychological stress and anxiety is another aspect which needs more consideration.

Low success rates: The Authority is concerned about the possible limited benefit of treatment at centres with a low throughput of patients and low success rates. A study will be undertaken and the Authority will need to consider what action to take in respect of any centres which are considered below standard.

Comparative success rates: The HFEA takes the view that publishing success rate data for individual IVF centres in simple terms of pregnancy and take-home baby rates could be misleading. Every patient is different and a number of factors can contribute to a couple's infertility. It could not be said that one centre is necessarily better than another for a couple's particular needs on a comparison of the centres' average success rates.

At the same time, the Authority recognises that IVF in particular can be both stressful and expensive and there is a legitimate demand from potential patients for information about centres' individual success rates. Now that the HFEA has a full year's validated data on its own register, it intends to give further consideration to the best way of presenting comparative statistical information about the success of IVF and DI treatment at different centres.

Donors: The HFE Act states that no payment may be made for gametes or embryos except in accordance with HFEA Directions. The Direction issued by the Authority in August 1991 regularised the position which prevailed when the HFEA took up its powers. That is to say, men were commonly paid up to £15 per donation, while women were sometimes offered benefits in the form of free treatment or sterilisation in exchange for donating eggs. At the time the Direction was issued the Authority made it clear that it would return to this issue within two or three years. A special working group has been set up and is currently looking at issues surrounding payment for both sperm and egg donors. Its terms of reference are to identify and discuss the ethical issues arising from the payment of donors and to report to the Authority on the methods of paying donors and the implications and whether withdrawal of payment in money or in kind would result in a shortage of donors.

The survey of semen donors has thrown some light on the motivation of male donors. The matter of women being offered free treatment in exchange for egg donation has recently attracted attention. The Authority's policy will be reviewed following recommendations by the Working Group on Payment of Donors. News of agents offering to act as go-betweens in the supply of egg donors for a fee has caused concern and the Authority has informed centres that they should not use these agents.

> “The Authority has always tried to balance the requirements of regulation with the need to minimise the cost imposed on the centres the Authority licenses”

Code of Practice on Enforcement

May 1994

The Authority is required by law to carry out certain regulatory and other functions. These necessarily carry cost implications. The HFEA recognises the need to balance the requirements of regulation against the need to contain costs. The *Code of Practice on Enforcement* sets out a number of commitments which the Authority has given (see 4.2).

SECTION 9:

INCOME AND EXPENDITURE

9.1 HFEA BUDGET

The Authority's budget for the financial year 1993/94 was set at £1.32 million. The Authority is constantly mindful of the need to keep its running costs to a minimum in order to limit licence fees as far as possible. All expenditure is carefully monitored to ensure that the best use is made of all resources and that the budget is used effectively. During the financial year there was a considerable increase in the work undertaken. As a result of this extra work and the Authority's increasingly high profile, additional staff were required and this will have an effect on the budget for 1994/95. The expenditure account for the 1993/94 financial year is at Annex 6.

9.2 LICENCE FEES

In March 1993 discussions with the Department of Health and the Treasury began about the amount of the Authority's expenditure to be funded from licence fees. In 1991/92 the level had been set at 50% so as to recoup the amount of expenditure which was attributable to the licensing function. At the time of writing, no new agreement has been reached for the current year and therefore the fees remain at £30 per IVF cycle and £7 per donor insemination cycle. These will need to be revised once the outcome of the current discussions is known.

“The clinics are required by law to provide their figures on performance”

Under the HFE Act the Authority is obliged to keep a detailed register of:

- the treatment of individual patients;
- the use made of all eggs or sperm provided by donors; and
- all outcomes of licensed treatments

The register has three purposes. First, the HFE Act permits anyone over the age of 18 to have access to limited information about their genetic background. This is perfectly sensible if there is a chance – however slight – that they may be genetically related to someone they want to marry. Second, it is a method of monitoring the work of treatment and research centres. Third, it provides statistics such as national pregnancy and live-birth rates.

***The Times*, 17 January 1994. An article by Jeremy Laurance, entitled “Move to monitor fertility clinics’ success”, discussed the possibility of publishing comparative success rates.**

SECTION 10:

DATA COLLECTION

10.1 INTRODUCTION

The Authority is required by law to collect data on the treatment it licenses in order to give information to children born as a result of licensed treatment. It also enables the Authority to monitor the provision of IVF and DI. The Authority is notified of every treatment cycle of IVF and DI initiated in the United Kingdom and produces national data.

Data collection is important, not just for the Authority, but also for scientists and clinicians interested in fertility treatment and, most particularly, for patients and people seeking treatment. The tables which are published here are intended to provide a picture of trends in IVF and DI. Where possible, the 1991 figures, which covered the period 1 August – 31 December 1991, have been included for comparison. Further tables are contained at Annex 7.

In September 1993 the Authority set up a working group to examine its present system of collecting and reporting on treatment data. Following the Working Group on Information's recommendations, the tables published this year are more comprehensive than those produced previously and it is hoped they will be helpful both to patients and to the continuing development of good practice at centres. In the future the Authority will be prepared to consider individual requests for statistical material.

Background Information

Infertility can be caused by a factor in the male, a factor in the female or a factor in both. The main causes are sperm disorders, abnormal ovulatory function or damage to the fallopian tubes. Less frequent causes include endometriosis, cervical mucus defects or uterine fibroids. A large group of couples have no detectable cause and are referred to as having "unexplained" infertility. There is a glossary of terms provided at Annex 8.

Abnormal ovulatory function is often successfully treated by hormonal drugs though some are complicated to use and involve a risk of multiple births from multiple ovulation. Cervical mucus defects can be overcome by intrauterine insemination of sperm, or with IVF or GIFT. Endometriosis may be treated by hormones or surgery, uterine fibroids can be removed surgically and some tubal damage is correctable by surgery though IVF is often needed to bypass the problem.

Sperm disorders are mostly not treatable and donor insemination is the most common treatment. Techniques are being developed however which will enable the male partner's sperm to be used where the sperm count is low or the sperm is of poor quality and where donor insemination would have previously been necessary.

The success of infertility treatment can be compared with the normal chance of natural conception in couples of proven fertility, on average 20-25% in each monthly cycle. While the chance of success for a couple is higher if they have a number of treatment cycles, many couples do not achieve a pregnancy.

The data published here is based on the treatment and outcome forms the HFEA receives. For the 1992 data, there were 404 outcome forms either not received or the information given on them was not complete (8.4% of all clinical pregnancies). The percentage reported in the last Annual Report for the previous year was 8.6%.

10.2 IVF TABLES
1 JANUARY 1992 – 31 DECEMBER 1992

The results for IVF are presented so as to take account of certain factors having appreciable effects on the outcome. These include the age of the woman, the use of ovarian stimulation and the transfer of frozen-thawed embryos. In the male factor group the results using donor sperm have been separated from the results using the partner's own sperm because they differ.

Donor eggs may be needed in various instances: young women with a premature menopause, women whose own eggs fail to fertilise or to avoid a risk of passing on a genetic disorder. Results with donor eggs have been separated when considering the woman's age in IVF results (see Table 5).

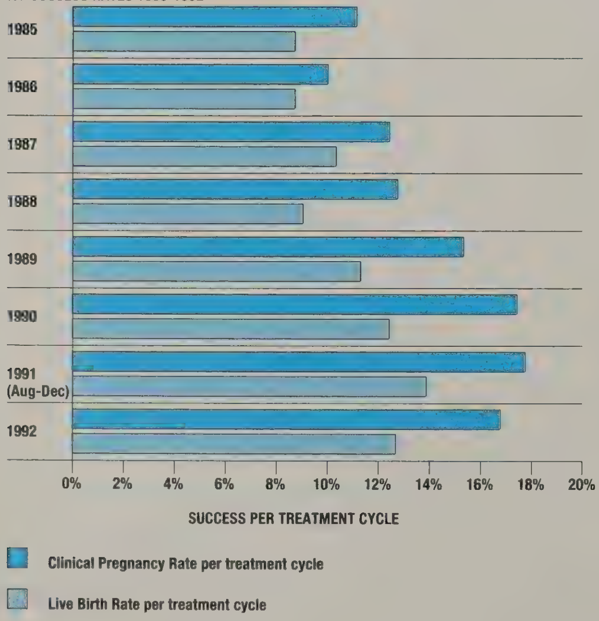
In 1992 25 centres were classified as large and 40 were classified as small (less than 300 cycles per annum). There is more variation in the results of small centres.

IVF Success Rates: 1985 – 1992

TABLE 1
IVF SUCCESS RATES: 1985-1992

	CLINICAL PREGNANCY RATE % Per Treatment Cycle	LIVE BIRTH RATE % Per Treatment Cycle
1985	11.2	8.6
1986	9.9	8.6
1987	12.5	10.1
1988	12.9	9.1
1989	15.4	11.1
1990	17.3	12.5
1991 (Aug-Dec)	17.8	13.9
1992	16.9	12.7

CHART 1
IVF SUCCESS RATES 1985-1992



The total number of IVF treatment cycles for 1992 was 18,224 (including frozen embryo transfers). There were 3,080 clinical pregnancies and 2,318 live births. These figures can be found in Tables 1, 2 and 3 of Annex 7.

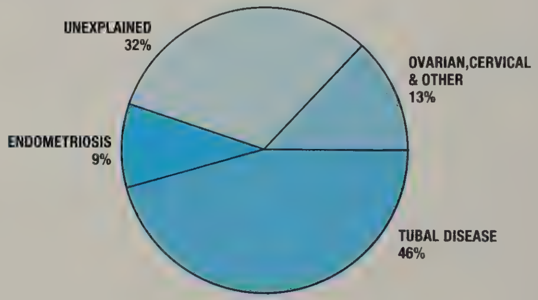
Both the overall clinical pregnancy rate and live birth rate for 1992 are lower than the rates published for 1991. For 1992 the clinical pregnancy rate is 16.9% (17.8%* in 1991) and the live birth rate is 12.7% (13.9%* in 1991).

Detailed analysis of the figures suggests that this may be due to the fact that the average age of women having treatment has increased. In 1992 women undergoing IVF treatment were, on average, 34 years of age, one year older than in 1991.

(* These figures differ slightly from the 1991 data published in last year's Annual Report as more data have become available for that period).

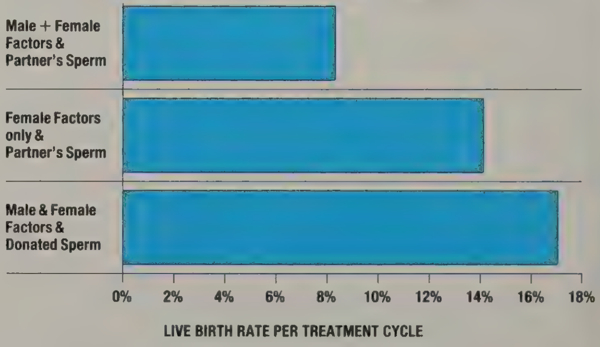
Indications for IVF Treatment

PIE CHART
IVF: FEMALE REASONS FOR TREATMENT



The pie chart shows the female indications for treatment. These different diagnoses of women referred for IVF treatment do not significantly affect the chances of a successful treatment.

IVF LIVE BIRTH RATES ACCORDING TO MALE FACTOR & DONATED OR PARTNER'S SPERM
(excluding Frozen Embryo Transfers, Unstimulated Cycles, Donated Eggs & Embryos)



The bar chart and table indicate that a significant factor is whether there is a problem with the partner's sperm. Over 70% of all treatments involving a female factor also recorded a male factor. Where the partner's sperm was used and there is a male factor, the live birth rate is 8.4% per treatment cycle compared with 17.1% where donor sperm was used. For those with no male factor the live birth rate is 14.1%.

TABLE 2
IVF SUCCESS RATES ACCORDING TO MALE FACTOR
(exluding Frozen Embryo Transfers, Unstimulated Cycles, Donated Eggs & Embryos)

Male Factor	Use of Donated Sperm*	Live Birth Rate%	No of Treatment Cycles
Yes	No	8.4	8585
No	No	14.1	4716
Yes	Yes	17.1	1305

*105 cycles excluded where donated sperm used but no male factor given

In Table 2 all frozen embryo transfers unstimulated cycles and cycles using donor eggs or donated embryos have been excluded to illustrate clearly the impact of a male factor on IVF success rates.

Mean Clinical Pregnancy and Live Birth Rates for Stimulated and Unstimulated Fresh IVF Cycles

TABLE 3A
MEAN CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)

		PREGNANCY RATES %		
	Number of Treatment Cycles	Per Treatment Cycle	Per Egg Collection	Per Transfer
Own Gametes	13301	17.0	19.2	22.7
Donor Sperm	1410	22.6	22.7	25.3
Donor Eggs	52	15.4	15.7	16.7
Donated Embryos	13	30.8	30.8	44.4
Combined Totals	14776	17.5		

		LIVE BIRTH RATES %		
	Number of Treatment Cycles	Per Treatment Cycle	Per Egg Collection	Per Transfer
Own Gametes		12.8	14.5	17.1
Donor Sperm		16.9	17.0	19.0
Donor Eggs		13.5	13.7	14.6
Donated Embryos		15.4	15.4	22.2
Combined Total		13.2		

TABLE 3B
MEAN CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)

		PREGNANCY RATES %		
	Number of Treatment Cycles	Per Treatment Cycle	Per Egg Collection	Per Transfer
Own Gametes	780	7.8	11.9	17.2
Donor Sperm	41	9.8	13.8	17.4
Donor Eggs	289	24.9	25.6	27.5
Donated Embryos	31	32.3	35.7	37.0
Combined Totals	1141	12.9		

		LIVE BIRTH RATES %		
	Number of Treatment Cycles	Per Treatment Cycle	Per Egg Collection	Per Transfer
Own Gametes		6.0	9.2	13.3
Donor Sperm		9.8	13.8	17.4
Donor Eggs		20.8	21.4	22.9
Donated Embryos		19.4	21.4	22.2
Combined Total		10.3		

These tables show results for 15,917 fresh IVF treatment cycles according to whether they were stimulated or unstimulated cycles and whether a couple's own eggs and sperm were used or donor eggs or sperm were used. In a small number of cases donated embryos were used. Clinical pregnancy rates and live birth rates are given per treatment cycle, per successful egg collection and per embryo transfer.

The highest live birth rates for stimulated cycles are found among women who had had IVF with donated embryos or with donor sperm. This may reflect the fact that many other couples treated with IVF have a male factor problem as well as a female factor.

A more detailed breakdown of this data can be found in the tables at Annex 7.

Mean Clinical Pregnancy and Live Birth Rates of Frozen Embryo Transfer Cycles

TABLE 4
MEAN CLINICAL PREGNANCY AND LIVE BIRTH RATES FOR FROZEN EMBRYO TRANSFER CYCLES (ALL CENTRES)

	Number of Embryo Transfers	CLINICAL PREGNANCY RATES % Per Embryo Transfer	LIVE BIRTH RATES % Per Embryo Transfer
Own Gametes	1901	14.8	10.9
Donor Sperm	249	13.7	9.2
Donor Eggs	108	19.4	13.9
Donated Embryos	49	22.4	16.3
Combined Totals	2307	15.0	11.0

A frozen embryo transfer is one in which the eggs are fertilised and the embryos are then frozen-stored; when needed, the embryos are removed from storage and thawed before transfer to the woman.

For 1992 there were 2,307 frozen-thawed embryo transfers. These resulted in 347 clinical pregnancies and 254 live births, a clinical pregnancy rate of 15% and a live birth rate of 11% per embryo transfer.

IVF Success Rates by Women's Age

TABLE 5A
IVF SUCCESS RATES BY WOMEN'S AGE USING OWN EGGS (ALL CENTRES)

	TREATMENT CYCLES	CLINICAL PREGNANCY RATES % Per Treatment Cycle	LIVE BIRTH RATES % Per Treatment Cycle
Under 25	178	16.9	9.6
25-29	2416	22.1	16.5
30-34	6806	19.0	14.6
35-39	6039	15.2	11.4
40-44	2065	8.2	4.5
45 and over	174	3.4	1.7

TABLE 5B
IVF SUCCESS RATES BY WOMEN'S AGE USING DONOR EGGS (ALL CENTRES)

	TREATMENT CYCLES	CLINICAL PREGNANCY RATES % Per Treatment Cycle	LIVE BIRTH RATES % Per Treatment Cycle
Under 25	8	37.5	37.5
25-29	55	16.4	7.3
30-34	134	27.6	20.9
35-39	128	25.8	24.2
40-44	142	16.9	12.7
45 and over	79	25.3	17.7

The woman's age is an important factor affecting the outcome of treatment when she uses her own eggs. The data for 1992 show that, except for women under 25, the likelihood of achieving a pregnancy and a live birth decreases with age. However, for women receiving donor eggs, the age of the patient appears less significant.

Single and Multiple Clinical Pregnancy Outcomes After IVF or Frozen Embryo Transfers

TABLE 6
SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES AFTER IVF OR FROZEN EMBRYO TRANSFERS (ALL CENTRES)

	SINGLETON	TWIN	TRIPLET	TOTALS
Clinical Pregnancies	2109	709	118	2936
Miscarriages	329	106	26	461
Terminations	0	1	6	7
Ectopics	46	7	0	53
Unknown Outcomes	111	20	1	132
Live Births	1592	627	99	2318
Babies Born	1603	1174	256	3033
Perinatal Deaths	25	25	18	68

This table excludes 132 unreturned outcome forms and 12 ectopic pregnancies where no fetal sacs were recorded.

The overall multiple clinical pregnancy rate for 1992 is slightly lower than the figures published in last year's Annual Report for 1991, 28.2% compared to 29.1%.

Of all clinical pregnancies reported for 1992, 71.8% were singleton, 24.1% were twin and 4% were triplet. For 1991 the comparative figures published were 70.9% singleton, 24.5% twin and 4.6% triplet. Table 4 at Annex 7 gives the number of embryos transferred in relation to the IVF multiple clinical pregnancy rate.

As a result of IVF treatment for 1992, 68.7% of live births were singleton, 27% were twin and 4.3% were triplet. The multiple birth rate is 31.3%.

The miscarriage rates for singleton and twin pregnancies are comparable, though the miscarriage rate for triplet pregnancies is greater.

According to the Office of Population and Census Surveys (OPCS), the rate of multiple births in the general population has increased since 1980 when it was 0.98% in England and Wales. By 1992 the rate had risen to 1.25%.

A similar increase has occurred in Scotland and Northern Ireland. This increase is believed to be due to the use of superovulatory drugs in fertility treatment (including non-licensable treatment).

There is concern about the physical, emotional and financial stresses associated with multiple pregnancies and births. The Authority will continue to monitor the rate of multiple pregnancies.

The perinatal mortality rate for IVF is higher than that of the general population*. This is attributed to the greater number of multiple births. The perinatal mortality rate for IVF has risen to 27.4 perinatal deaths per 1000 live births from 19.3 per 1000 in 1991**. Though this is a large rise, the figures are too small for firm conclusions to be drawn. The Authority will monitor these figures closely.

(* The figure for the general population of England and Wales in 1992 was 8 perinatal deaths per 1000 live births)

(** This figure differs slightly from the 1991 data published in last year's Annual Report as more data have become available for that period).

10.3 DONOR INSEMINATION TABLES: 1 JANUARY 1992 – 31 DECEMBER 1992

The term donor insemination is used in this context to cover the relatively simple insemination of donor sperm into the woman as well as GIFT, IUI and any other non-IVF procedures in which donor sperm is used.

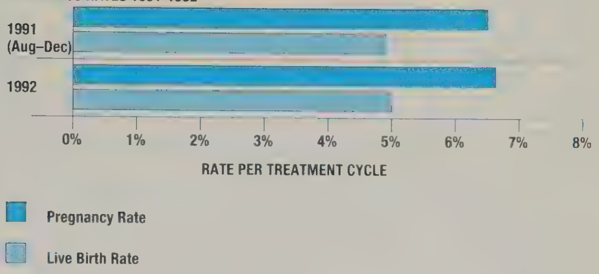
The use of donor sperm is commonly required because of infertility due to untreatable sperm disorders or to avoid genetic abnormalities which could be inherited from the father.

DI Clinical Pregnancy and Live Birth Rates per Treatment Cycle 1991 – 1992

TABLE 7
DI CLINICAL PREGNANCY & LIVE BIRTH RATES PER TREATMENT CYCLE 1991-1992

	PREGNANCY RATE %	LIVE BIRTH RATE %
1991 (Aug-Dec only)	6.5	4.9
1992	6.7	5.0

DI SUCCESS RATES 1991-1992



This is the first year that a full twelve months data for DI success rates have been available. The figures reported for 1991* were a 6.5% clinical pregnancy rate per treatment cycle and a 4.9% live birth rate per treatment cycle. The clinical pregnancy rate for 1992 is 6.7% per treatment cycle and the live birth rate is 5.0% per treatment cycle.

(* These figures differ slightly from the 1991 data published in last year's Annual Report as more data have become available for that period).

DI Data

TABLE 8
DI DATA (ALL CENTRES)

UNSTIMULATED CYCLES	
Number of Centres	87
Number of Patients	4550
Number of Treatment Cycles	16024
Total Clinical Pregnancies	1023
Clinical Pregnancy Rate per Cycle	6.4%
Total Miscarriages	130
Total Terminations	3
Total Ectopics	4
Total Live Births	797
Live Birth Rate per Cycle	5.0%
Total Perinatal Deaths	9

STIMULATED CYCLES	
Number of Centres	93
Number of Patients	3361
Number of Treatment Cycles	10039
Total Clinical Pregnancies	711
Clinical Pregnancy Rate per Cycle	7.1%
Total Miscarriages	114
Total Terminations	2
Total Ectopics	7
Total Live Births	509
Live Birth Rate per Cycle	5.1%
Total Perinatal Deaths	8

Ovulation is sometimes stimulated to try to improve the chance of success of DI treatment. It is evident from the table that there is a slightly lower chance of conceiving if a woman has a natural (unstimulated) cycle with DI compared with a stimulated cycle (6.4% and 7.1% respectively). However, the live birth rate is virtually the same for unstimulated and stimulated DI cycles (5.0% and 5.1% respectively).

The miscarriage rate and the perinatal death rate are higher for stimulated cycles. This increase may be attributed to the higher multiple birth rate for stimulated cycles. The number of ectopic pregnancies is also higher for stimulated compared with unstimulated cycles.

DI Success Rates by Women's Age

TABLE 9
DI SUCCESS RATES BY WOMEN'S AGE (ALL CENTRES)

	TREATMENT CYCLES	CLINICAL PREGNANCY RATES % Per Treatment Cycle	LIVE BIRTH RATES % Per Treatment Cycle
Under 25	935	9.0	7.0
25-29	6609	7.3	5.6
30-34	10326	7.0	5.4
35-39	6343	5.8	4.1
40-44	1770	4.1	2.0
45 and over	80	3.8	1.3

The data for 1992 show that the likelihood of a woman achieving a pregnancy and a live birth decreases with age.

Single and Multiple Clinical Pregnancy Outcomes for Stimulated and Unstimulated DI

TABLE 10A
SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR STIMULATED DI (ALL CENTRES)

	SINGLETON	TWIN	TRIPLET	QUAD	TOTALS
Clinical Pregnancies	564	77	10	1	652
Miscarriages	104	10	0	0	114
Terminations	2	0	0	0	2
Ectopics	7	0	0	0	7
Unknown Outcomes	16	2	0	0	18
Live Births	431	67	10	1	509
Babies Born	432	131	28	4	595
Perinatal Deaths	5	1	0	0	8

TABLE 10B
SINGLE AND MULTIPLE CLINICAL PREGNANCY OUTCOMES FOR UNSTIMULATED DI (ALL CENTRES)

	SINGLETON	TWIN	TRIPLET OR GREATER	TOTALS
Clinical Pregnancies	963	16	0	979
Miscarriages	129	1	0	130
Terminations	3	0	0	3
Ectopics	4	0	0	4
Unknown Outcomes	38	0	0	38
Live Births	781	16	0	797
Babies Born	782	31	0	813
Perinatal Deaths	9	0	0	9

This table excludes 101 unreturned outcome forms and 2 ectopic pregnancies where no fetal sacs were recorded

The overall multiple clinical pregnancy rate for donor insemination is lower than that of IVF. For stimulated cycles, the multiple clinical pregnancy rate for DI was 13.5% and the multiple birth rate was 15.3%. For unstimulated cycles the rates were 1.6% and 2.0% respectively. (The multiple birth rate is higher than the multiple clinical pregnancy rate due to the fact that most multiple pregnancies resulted in live births.)

Of all DI clinical pregnancies reported for 1992, 93.6% were singleton, 5.7% were twin, 0.6% were triplet and 0.1% were quadruplet. For 1991 the comparative figures published were 94.1% singleton, 5.4% twin and 0.5% triplet. The overall multiple DI clinical pregnancy rate published last year was 5.9% and for 1992 it is 6.4%.

As a result of DI treatment for 1992, 92.8% of live births were singleton, 6.4% were twin, 0.8% were triplet and 0.1% were quadruplet.

As for IVF the Authority will monitor the multiple birth rates for donor insemination.

&

ANNEX 1:

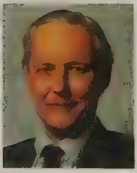
MEMBERSHIP OF THE HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY

Professor Sir Colin Campbell
Vice-Chancellor,
Nottingham University

Lady Diana Brittan
Member, Equal Opportunities Commission;
Magistrate, City of London;
Chairman, Community Industry

Professor Robert Berry
Professor of Genetics,
University College, London

Professor Ian Cooke
Professor of Obstetrics & Gynaecology, University of Sheffield, Jessop Hospital for Women



Professor Antony Cox
Professor of Child & Adolescent Psychiatry, United Medical & Dental Schools of Guy's & St Thomas's Hospitals

Jane Denton
Nursing Director, Multiple Births Foundation
Queen Charlottes & Chelsea Hospital, London

Liz Forgan
Managing Director,
BBC Radio

Joan Harbison
Senior Lecturer in Education,
Stranmillis College, Belfast

Professor Stephen Hillier
Professor of Reproductive Endocrinology,
University of Edinburgh

The Most Reverend Richard Holloway
Bishop of Edinburgh

Professor Martin Johnson
Professor of Reproductive Sciences,
University of Cambridge

Penelope Keith
Actress

Dr Brian Lieberman
Medical Director,
Regional IVF and DI Unit
St Mary's Hospital,
Manchester

Angela Mays
Management Consultant

Dr Anne McLaren
Principal Research Associate,
Wellcome CRC Institute

Dr Jeannette Naish
General Practitioner;
Senior Lecturer, Department of General Practice & Primary Care, Medical College of St Bartholomew and the London Hospitals,
University of London

Rabbi Julia Neuberger
Chairman, Camden & Islington Community Health Services NHS Trust

David Shilson
Senior Official,
Bank of England

Julia Tugendhat
Family Therapist,
Westminster Pastoral Foundation

ANNEX 2:

MEMBERS OF HFEA COMMITTEES AND WORKING GROUPS

Those listed are Members of the Authority unless otherwise stated

LICENSING AND FEES COMMITTEE

Diana Brittan *(Chairman)*
Jane Denton
Stephen Hillier
Richard Holloway
Martin Johnson
Brian Lieberman
Angela Mays
Julia Neuberger
David Shilson

CODE OF PRACTICE COMMITTEE

Robert Berry *(Chairman)*
Ian Cooke
Antony Cox
Liz Forgan
Joan Harbison
Penelope Keith
Anne McLaren
Jeannette Naish
Julia Tugendhat

ORGANISATION AND FINANCE COMMITTEE

Colin Campbell *(Chairman)*
Diana Brittan
Robert Berry
David Shilson

WORKING GROUP ON EMBRYO FREEZING

Stephen Hillier *(Chairman)*
Albert Bernard
University of Wales, College of Medicine
Robert Berry
Jane Denton
Lynn Fraser
King's College, London
Alison Murdoch
Centre for Reproductive Medicine, Newcastle

WORKING GROUP ON INFORMATION

Antony Cox *(Chairman)*
Diana Brittan
Chris Barratt
University of Sheffield
Michael Hull
St Michael's Hospital, Bristol
Angela Mays
Joan Morris
Wolfson Institute of Preventive Medicine
Susan Smith *(Oct 93 – Mar 94)*
Bridge Fertility Centre

WORKING GROUP ON PAYMENT OF DONORS

Joan Harbison *(Chairman)*
Jane Denton
Martin Johnson
Brian Lieberman
Angela Mays
Jeannette Naish
David Shilson

WORKING GROUP ON TRAINING IN INFERTILITY COUNSELLING

Julia Neuberger *(Chairman)*
Judith Baron *BAC*
Eric Blyth *PROGAR*
Robert Bor *BPS*
John Dickson *ISSUE*
Jennifer Hunt *BICA*
Margaret Inglis *Counsellor*
Sue Jennings *Counsellor*
Malcolm Macnaughton *HFEA Inspector*
Iris Singer *BAAF*
Marj Thoburn *RELATE*
Julia Tugendhat
Alexina McWhinnie *University of Dundee*

ANNEX 3:

LIST OF CENTRES CURRENTLY LICENSED BY THE HFEA FOR TREATMENT

AVON
Royal United Hospital, Bath
St Michael's Hospital, Bristol
Southmead General Hospital, Bristol
Tower House Clinic, Bristol
University of Bristol IVF Service, BUPA Glenn Hospital

BERKSHIRE
Berkshire Fertility Centre, Reading

BUCKINGHAMSHIRE
The BMI Chiltern Hospital, Great Missenden

CAMBRIDGESHIRE
Bourn Hall Clinic, Cambridge
Rosie Maternity Hospital, Cambridge

CLEVELAND
Hartlepool General Hospital
South Cleveland Hospital, Middlesbrough
Cleveland Nuffield Fertility Centre, Stockton-on-Tees
Cleveland Fertility Centre, Stokesley

DEVON
Royal Devon & Exeter Hospital
Nuffield Hospital, Plymouth

DORSET
The Winterbourne Hospital, Dorchester

ESSEX
Holly House Hospital, Buckhurst Hill
BUPA Roding Hospital, Ilford
North East London Fertility Services, Ilford

HAMPSHIRE
Basingstoke District Hospital
BUPA Chalybeate Hospital, Southampton
Princess Anne Hospital, Southampton

HERTFORDSHIRE
Watford General Hospital

HUMBERSIDE
Princess Royal Hospital, Hull

KENT
Chelsfield Park Hospital
Maidstone District General Hospital
Queen Mary's Hospital, Sidcup

LANCASHIRE
Manchester Fertility Services, Manchester BUPA Hospital
St Mary's Hospital, Manchester
Withington Hospital, Manchester
Hope Hospital, Salford
Billinge Hospital, Wigan
Royal Albert & Edward Infirmary, Wigan

LEICESTERSHIRE
BUPA Hospital, Leicester
Leicester Royal Infirmary

MERSEYSIDE
Fazakerley Hospital, Liverpool
Royal Liverpool University Hospital
The Rodney Fertility Clinic, Liverpool
The Women's Hospital, Liverpool
BUPA Murrayfield Hospital, Wirral

MIDDLESEX
West Middlesex University Hospital, Isleworth

MIDLANDS (WEST)
Midland Fertility Services, Aldridge
BMI Priory Hospital, Birmingham
Birmingham Maternity Hospital
SAI Walsall Medical Centre

NORFOLK
BUPA Hospital, Norwich

NORTHAMPTON
Three Shires Hospital, Cliftonville

NOTTINGHAMSHIRE
BMI Park Hospital, Arnold
Nottingham City Hospital
NURTURE, University of Nottingham

OXFORDSHIRE
Churchill Hospital, Headington
John Radcliffe Hospital, Headington

STAFFORDSHIRE
North Staffordshire Maternity Hospital, Stoke-on-Trent

SUSSEX (EAST)
Esperance Private Hospital, Eastbourne

TYNE AND WEAR
Centre for Reproductive Medicine, Newcastle upon Tyne
Sunderland District General Hospital
Cromwell IVF & Fertility Centre, Washington Hospital

WARWICKSHIRE
Walsgrave Hospital, Coventry

YORKSHIRE (SOUTH)
Doncaster Infertility Services
Jessop Hospital for Women, Sheffield
Sheffield Fertility Centre

YORKSHIRE (WEST)
Clarendon Wing, Leeds General Infirmary
St. James's University Hospital Trust, Leeds

LONDON (CENTRAL)
Bridge Fertility Centre, London Bridge Hospital
Dr G B Caruthers, Wimpole Street
The Churchill Clinic
Clinic of Reproductive Medicine, UCH
Cromwell Hospital
Cromwell – St George's Fertility Centre,
St George's Hospital
Dr Louis Hughes, Harley Street
Lister Hospital
London Fertility & Gynaecology Centres (2)
London Womens' Clinics/Hallam Medical Centres (4)
Middlesex Hospital
Portland Hospital Fertility Unit
Pregnancy Advisory Service
St Bartholomew's Hospital
St Thomas's Hospital
University College Hospital (UCH)

LONDON (EAST)
Newham General Hospital
The Rowan Clinic, Royal London Hospital

LONDON (NORTH)
Highgate Private Hospital

LONDON (SOUTH)
King's College Hospital

LONDON (WEST)
Hammersmith Hospital
Queen Charlotte's & Chelsea Hospital
Royal Masonic Hospital

NORTHERN IRELAND
Royal Maternity Hospital, Belfast

SCOTLAND
Aberdeen Maternity Hospital
Monklands District General Hospital, Airdrie
Ninewells Hospital, Dundee
Royal Infirmary of Edinburgh
Western General Hospital, Edinburgh
Glasgow Nuffield Hospital
Glasgow Royal Infirmary Hospital
Glasgow Royal Maternity Hospital
Ross Hall BMI Hospital, Glasgow
Raigmore Hospital, Inverness
Balfour Hospital, Orkney

WALES
University Hospital of Wales, Cardiff
Neath General Hospital
Singleton Hospital, Swansea

CENTRE PROVIDING HAMSTER EGG PENETRATION TEST (HEPT) ONLY
London Andrology Centre

CENTRES WITH STORAGE LICENCES ONLY
St David's Hospital, Bangor
Royal Sussex County Hospital, Brighton
Danum Lodge, Doncaster
Blackdown Nursing Home, Leamington Spa
Bridge Fertility Centre Cryoservices, London
Diagnostic Andrology Services, London (also HEPT)
St George's Hospital Medical School, London
Walm Lane Clinic, London
Newcastle General Hospital
Nottingham City Hospital
SCIPAC, Sittingbourne

ANNEX 4:

LIST OF CURRENT RESEARCH PROJECTS

BRIDGE FERTILITY CENTRE, LONDON

Comparison of ICSI and re-insemination for the fertilisation of 24-hour old unfertilised eggs

CENTRE FOR REPRODUCTIVE MEDICINE, NEWCASTLE UPON TYNE

A study of the role of intracellular calcium in the development of human pre-implantation embryos

EDINBURGH ROYAL INFIRMARY

Cell biology of human spermatozoa

HAMMERSMITH HOSPITAL, LONDON

To measure the activity of metabolic enzymes in spare human pre-implantation embryos

To measure the activity of enzymes implicated in genetic disorders

Sperm/oocyte interaction and fertilisation failure

Pre-implantation genetic diagnosis parallel investigations

JESSOP HOSPITAL FOR WOMEN, SHEFFIELD

Investigation of the effects of immuno-modulatory factors on implantation *in vitro*

KINGS COLLEGE HOSPITAL, LONDON

Pre-implantation stage diagnosis of sickle cell anaemia and haemophilia A in the human embryo

Investigation of chromosomal abnormalities in human oocytes and preimplantation embryos

The role of growth factors in human preimplantation embryogenesis

Investigation of the relationship between patterns of protein synthetic activity and the viability of human oocytes and preimplantation diagnosis

Investigation of the effects of co-culture with the endometrial cells on the viability of human pre-implantation embryos

Investigation of the role of protein kinases in cleavage of one cell human pre-implantation embryos

Investigation of the effects of fluctuations in pH and temperature on the viability of human oocytes and pre-implantation embryos

Investigation of the effect of different culture components on the viability of human pre-implantation embryos *in vitro*

LEEDS GENERAL INFIRMARY

The use of human embryos to develop pre-implantation diagnosis techniques

Incidence of activation of aged human oocytes following ICSI both with and without sperm

LONDON WOMEN'S CLINIC HALLAM MEDICAL CENTRE

Intracytoplasmic single sperm injection of 1-day old unfertilised human oocytes and the culture of any embryos generated for 6 days post injection to monitor their development

JOHN RADCLIFFE HOSPITAL, OXFORDSHIRE

Transplantation antigen expression of human pre-implantation embryos

Biopsy of human embryos for the pre-implantation diagnosis of genetic disease

Pre-clinical study of human embryo cryopreservation

The use of growth factors to improve human embryo culture for *in vitro* fertilisation

A study of fertilisation by micromanipulation

ROYAL LIVERPOOL UNIVERSITY HOSPITAL

Measurement of intracellular metabolites at fertilisation

Immunobiological investigations into human fertilisation and implantation

The definition of optimal culture conditions for human pre-implantation embryo development *in vitro*

ST BARTHOLOMEW'S HOSPITAL, LONDON

Release of lymphokines by the human embryo

ST MICHAEL'S HOSPITAL, BRISTOL

Effects of substances and procedures on the ability of human spermatozoa to penetrate zona free hamster eggs

ST THOMAS'S HOSPITAL, LONDON

Methods for evaluating normality of pre-implantation development

Studies of methods for the cryopreservation of human oocytes

The use of unfertilised human oocytes to assess the fertilising ability of human spermatozoa via ICSI

UNIVERSITY COLLEGE HOSPITAL, LONDON

Pre-implantation diagnosis of genetic disease

UNIVERSITY OF ABERDEEN

Pre-implantation diagnosis of genetic disease

Development of micromanipulation assisted techniques for male factor infertility

Human oocyte preservation

UNIVERSITY OF WARWICK

Use of co-cultures in human IVF

WALSGRAVE HOSPITAL, COVENTRY

Use of co-cultures in human IVF

WITHINGTON HOSPITAL, MANCHESTER

In vitro development and implantation of normal human pre-embryos and comparison with uni- or poly-nucleate pre-embryos

ANNEX 5:

LIST OF CURRENT HFEA INSPECTORS

Professor John Aitken
Scientist, MRC Reproductive Biology Unit, Edinburgh

Dr Linda Baggott
Lecturer in Biology, University of Exeter

Professor David Barlow
Nuffield Professor of Obstetrics & Gynaecology, John Radcliffe Hospital, Oxfordshire

Professor Jem Berry
Consultant Paediatric Pathologist, Bristol Royal Hospital for Sick Children

Mrs Sarah Biggs
Former Vice-Chairman of CHILD; Formerly member of the Kings Fund Committee on Counselling

Professor Peter Braude
Chairman, Division of Obstetrics & Gynaecology, UMDS of Guy's & St Thomas's Hospitals, London

Mrs Linda Breeze
Counsellor for National Childbirth Trust and RELATE

Dr Nigel Brown
Scientist, MRC Experimental Embryology and Teratology Unit, London

Dr Elizabeth Bryan
Medical Director, Multiple Births Foundation

Mr Chris Chandler
Clinician, Billinge Hospital, Wigan

Dr Ann Clarke
University Research Fellow, Queen's Medical Centre, University of Nottingham

Dr John Clarke
Retired lecturer in Zoology, Oxford; Formerly Chairman of the Society for the Study of Fertility; Formerly member of the ILA

Dr Sheila Cooke
Counsellor, Manager of DI Unit; Formerly GP and Family Planning Doctor

Dr John Coutts
Reader in Reproductive Endocrinology, University of Glasgow

Mrs Alwyne Cox
Magistrate; Formerly member of National Council for the Probation Service; Formerly member of the ILA

Dr Ruth Curson
Associate Specialist, King's College Hospital, London

Ms Karin Dawson
Consultant Embryologist, Hammersmith Hospital, London

Ms Hilary Everett
Social Worker/Counsellor, St Bartholomew's Hospital, London

Dr Richard Fleming
Scientist, Glasgow Royal Infirmary

Professor Stephen Franks
Professor of Reproductive Endocrinology, St Mary's Hospital, London

Professor Lynn Fraser
Professor of Reproductive Biology, King's College, London; Chairman of the Society for the Study of Fertility

Professor Christine Gosden
Scientist, MRC, Human Genetics Unit, Edinburgh

Mrs Haideh Hillier
IVF Nurse Manager, Edinburgh Assisted Conception Unit

Professor Michael Hull
Consultant Obstetrician and Gynaecologist, St Michael's Hospital, Bristol

Ms Jennifer Hunt
Infertility Counsellor, Hammersmith Hospital, London

Ms Margaret Inglis
Counsellor, Royal Free Hospital, London

Ms Janice Kerr
Clinical Nurse Specialist (Infertility), Leeds

Dr Henry Leese
Scientist, Department of Biology, University of York

Dr Elizabeth Lenton
Senior Lecturer in Reproductive Endocrinology; Director, Sheffield Fertility Centre

Professor Sir Malcolm Macnaughton
Formerly President of the RCOG; Formerly member of the ILA; Formerly Professor of Obstetrics and Gynaecology, Glasgow Royal Infirmary

Dr Phil Matson
Consultant Embryologist, Regional IVF Unit, St Mary's Hospital, Manchester

Dr Alan McDermot
Director, Regional Cytogenetics Centre, Southmead Hospital, Bristol

Dr John Mills
Consultant Gynaecologist, Ninewells Hospital, Dundee

Professor Norman Nevin
Professor of Medical Genetics, Queens University, Belfast

Professor John Newton
Head of Department of Obstetrics and Gynaecology, Birmingham Maternity Hospital

Ms Vicki Nix
Royal College of Nursing

Ms Kathryn Parkinson
Unit Manager of IVF & OPD, BMI Portland Hospital, London

Mr John Parsons
Consultant Gynaecologist, King's College Hospital, London

Dr Michael Patten
Reader in Medical Genetics, St George's Hospital Medical School, London

Professor Charles Rodeck
Professor of Obstetrics & Gynaecology, University College Hospital London Medical School

Mr Robert Sawers
Birmingham and Midland Hospital for Women

Ms Annette Sayburn
Director of Clinical Services, BMI Portland Hospital, London

Dr Mary Seller
Reader in Development Genetics, Medical & Molecular Genetics, Guy's Hospital, London

Mrs Felicity Sieghart
Justice of the Peace, London

Dr Eric Simons
Medical Director, Cromwell Hospital, London

Ms Jennifer Speirs
Director, Family Care, Edinburgh

Professor Alan Templeton
Clinician, Department of Obstetrics & Gynaecology, Aberdeen Maternity Hospital

Professor William Thompson
Professor of Obstetrics & Gynaecology, Queens University, Belfast; Formerly member of the ILA; Formerly Chairman of the RCOG Fertility Sub-Committee

Mr Andy Walker
Director of Midland Fertility Services

Mrs Sheila Walker
Senior Lecturer and Director of IVF Unit, University Hospital of Wales, Cardiff

Dr Peter Wardle
Consultant Senior Lecturer, St Michael's Hospital, Bristol

Dr Paul Watson
Senior Lecturer in Veterinary Basic Sciences, Royal Veterinary College, London

Dr Christine West
Consultant Obstetrician & Gynaecologist, Royal Infirmary, Edinburgh

Dr Sarah West
Principal Scientific Officer, Northern Region Genetics Service, Newcastle

Dr Maureen Wood
Senior Scientific Officer, MRC Experimental Embryology & Teratology Unit, London

Dr Robert Yates
Medical Research Director of Assisted Conception Unit, Royal Infirmary, Glasgow

ANNEX 6:

HFEA ACCRUALS ACCOUNTS 1992/93

GROSS INCOME	£	£	£
Government grant			310,963
Income from licensing			686,040
Income from other sources			13,114
			1,010,117
TRANSFER FROM RESERVES			30,416
			1,040,533
EXPENDITURE			
Staff costs	413,603		
Depreciation	30,416		
Other operating charges**	582,558		
			1,026,577
Operating Surplus			13,956
Income from Investments			3,468
Surplus for the Financial Year			17,424
Appropriations			(13,094)
			4,330
Retained surplus brought forward			83,597
Retained surplus carried forward			87,927
OTHER OPERATING CHARGES**			
Accommodation		128,314	
Travel & Subsistence – Employees		6,390	
Travel & Subsistence – Members		21,807	
Travel & Subsistence – Inspectors		56,532	
Attendance Fees – Inspectors		32,066	
Professional & Administrative Fees		49,632	
Audit Fees		16,000	
Register of Information		67,839	
Stationery & Printing		39,278	
Photocopying Charges		10,665	
Telephones & Postage		22,496	
Communications		78,610	
Training & Staff Development		9,096	
Recruitment & Advertising		5,878	
Conferences & Meeting Expenses		16,423	
Library & Reading Materials		9,126	
Sundry Office Equipment		10,223	
Bad Debts		2,183	
Total		582,558	

The fees paid to inspectors include a provision of £3,015 for employers' National Insurance contributions.

A copy of the Authority's full accounts is available from HMSO

ANNEX 7:

1992 HFEA IVF AND DI TABLES OF SPECIALIST INTEREST

TABLE 1A
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)
(All percentages are of number of treatment cycles)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	9664	1198	51	12	10925
Treatment Cycles	13301	1410	52	13	14776
Cancelled/Failed Egg Collections	1564 (11.8%)	6 (0.4%)	1 (1.9%)	0 (0%)	1571 (10.6%)
Embryo Transfers	9930 (74.7%)	1255 (89%)	48 (92.3%)	9 (69.2%)	11242 (76.1%)
Clinical Pregnancies	2256 (17%)	318 (22.6%)	8 (15.4%)	4 (30.8%)	2586 (17 5%)
Miscarriages	323	59	0	2	384
Terminations	12	3	0	0	15
Ectopics	53	5	0	0	58
Unknown	194	24	1	1	220
Live Births	1700 (12.8%)	238 (16.9%)	7 (13.5%)	2 (15.4%)	1947 (13.2%)
Babies Born	2248	319	9	2	2578
Perinatal Deaths	58	7	0	0	65

TABLE 1B
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (LARGE CENTRES)
(All percentages are of number of treatment cycles)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	7445	838	36	9	8328
Treatment Cycles	9130	978	36	10	10154
Cancelled/Failed Egg Collections	1124 (12.3%)	2 (0.2%)	0 (0%)	0 (0%)	1126 (1.11%)
Embryo Transfers	6750 (73.9%)	872 (89.2%)	33 (91.7%)	6 (60%)	7661 (75.4%)
Clinical Pregnancies	1702 (18.6%)	231 (23.6%)	7 (19.4%)	3 (30%)	1943 (19.1%)
Miscarriages	243	34	0	2	279
Terminations	11	3	0	0	14
Ectopics	41	4	0	0	45
Unknown	143	19	1	0	163
Live Births	1287 (14.1%)	178 (18.2%)	6 (16 7%)	2 (20%)	1473 (14.5%)
Babies Born	1721	241	8	2	1972
Perinatal Deaths	46	2	0	0	48

TABLE 1C
RESULTS OF STIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (SMALL CENTRES)
(All percentages are of number of treatment cycles)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	2219	360	15	3	2597
Treatment Cycles	4171	432	16	3	4622
Cancelled/Failed Egg Collections	440 (10.5%)	4 (0.9%)	1 (6.3%)	0 (0%)	445 (9.6%)
Embryo Transfers	3180 (76.2%)	383 (88.7%)	15 (93 8%)	3 (100%)	3581 (77.5%)
Clinical Pregnancies	554 (13.3%)	87 (20.1%)	1 (6.3%)	1 (33.3%)	643 (13 9%)
Miscarriages	80	25	0	0	105
Terminations	1	0	0	0	1
Ectopics	12	1	0	0	13
Unknown	51	5	0	1	57
Live Births	413 (9.9%)	60 (13 9%)	1 (6 3%)	0 (0%)	474 (10 3%)
Babies Born	527	78	1	0	606
Perinatal Deaths	12	5	0	0	17

TABLE 2A
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (ALL CENTRES)
(All percentages are of number of treatment cycles)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	631	38	261	28	958
Treatment Cycles	780	41	289	31	1141
Cancelled/Failed Egg Collections	268 (34.4%)	12 (29.3%)	8 (2.8%)	3 (9.7%)	291 (25.5%)
Embryo Transfers	354 (45.4%)	23 (56.1%)	262 (90.7%)	27 (87 1%)	666 (58.4%)
Clinical Pregnancies	61 (7.8%)	4 (9.8%)	72 (24.9%)	10 (32.3%)	147 (12.9%)
Miscarriages	8	0	6	0	14
Terminations	0	0	0	2	2
Ectopics	2	0	1	2	5
Unknown	5	0	6	0	11
Live Births	47 (6%)	4 (9 8%)	60 (20.8%)	6 (19.4%)	117 (10.3%)
Babies Born	53	5	87	6	151
Perinatal Deaths	0	0	0	2	2

TABLE 2B
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (LARGE CENTRES)
(All percentages are of number of treatment cycles)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	569	32	208	21	830
Treatment Cycles	697	34	225	22	978
Cancelled/Failed Egg Collections	240 (34.4%)	11 (32.4%)	8 (3.6%)	2 (9.1%)	261 (26.7%)
Embryo Transfers	310 (44.5%)	17 (50%)	201 (89 3%)	20 (90 9%)	548 (56%)
Clinical Pregnancies	55 (7.9%)	3 (8.8%)	61 (27 1%)	8 (36 4%)	127 (13%)
Miscarriages	8	0	5	0	13
Terminations	0	0	0	2	2
Ectopics	2	0	1	1	4
Unknown	3	0	6	0	9
Live Births	43 (6 2%)	3 (8 8%)	50 (22 2%)	5 (22 7%)	101 (10 3%)
Babies Born	49	4	74	5	132
Perinatal Deaths	0	0	0	2	2

TABLE 2C
RESULTS OF UNSTIMULATED IVF AND FRESH EMBRYO TRANSFER CYCLES (SMALL CENTRES)
(All percentages are of number of treatment cycles)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	62	6	53	7	128
Treatment Cycles	83	7	64	9	163
Cancelled/Failed Egg Collections	28 (33.7%)	1 (14.3%)	0 (0%)	1 (11.1%)	30 (18.4%)
Embryo Transfers	44 (53%)	6 (85 7%)	61 (95 3%)	7 (77 8%)	118 (72.4%)
Clinical Pregnancies	6 (7.2%)	1 (14.3%)	11 (17.2%)	2 (22 2%)	20 (12.3%)
Miscarriages	0	0	1	0	1
Terminations	0	0	0	0	0
Ectopics	0	0	0	1	1
Unknown	2	0	0	0	2
Live Births	4 (4.8%)	1 (14.3%)	10 (15 6%)	1 (11.1%)	16 (9.8%)
Babies Born	4	1	13	1	19
Perinatal Deaths	0	0	0	0	0

TABLE 3
RESULTS OF FROZEN EMBRYO TRANSFER CYCLES (ALL CENTRES)
(All percentages are of number of embryo transfers)

	OWN GAMETES	DONOR SPERM	DONOR EGGS	DONATED EMBRYOS	TOTALS
Patients	1554	217	95	42	1908
Embryo Transfers	1901	249	108	49	2307
Clinical Pregnancies	281 (14.8%)	34 (13.7%)	21 (19.4%)	11 (22.4%)	347 (15%)
Miscarriages	49	8	4	2	63
Terminations	1	0	0	0	1
Ectopics	2	0	0	0	2
Unknown	27	3	2	1	33
Live Births	208 (10.9%)	23 (9.2%)	15 (13.9%)	8 (16.3%)	254 (11%)
Babies Born	245	28	20	11	304
Perinatal Deaths	1	0	0	0	1

TABLE 4A
IVF MULTIPLE CLINICAL PREGNANCY AND EMBRYO TRANSFER
(for all centres, including Frozen Embryo Transfers)

EMBRYOS TRANSFERRED	NO OF TRANSFERS	SINGLETON	TWIN	TRIPLET
One	1869	154	3	1
Two	4279	687	193	1
Three	8067	1268	513	116
Totals	14215	2109	709	118

TABLE 4B
IVF CLINICAL PREGNANCY AND MULTIPLE CLINICAL PREGNANCY RATES PER EMBRYO TRANSFER (for all centres, including Frozen Embryo Transfers)

EMBRYOS TRANSFERRED	CLINICAL PREGNANCY RATES %	MULTIPLE CLINICAL PREGNANCY RATES %
One	8.5	2.5
Two	20.6	22.0
Three	23.5	33.2

TABLE 5
DEVELOPMENTAL DEFECTS & SYNDROMES

CHROMOSOMAL SYNDROMES	**NO OF BIRTHS**
Down's syndrome	10
Other chromosomal anomalies	1
Haemophilia	1
CONGENITAL ABNORMALITIES	
Hydrocephalus	1
Encephalocele	1
Other anomalies nervous system	2
Other anomalies of the eye	1
Ear anomalies	1
Cleft palate	1
Cleft lip	1
Cleft lip with cleft palate	2
Tracheo-oesophageal fistula	2
Atresia, stenosis large intestine	3
Anomalies of alimentary system	2
Cardiac murmurs	1
Ventricular septal defects	2
Other congenital cardiac anomalies	6
Patent ductus	1
Anomalies of umbilical vessels	1
Congenital anomalies of circulatory system	1
Hypospadias, Epispadias	5
Renal anomalies	5
Anomalies of urogenital system	2
Polydactyly or syndactyly	4
Talipes	3
Congenital dislocation of hip	1
Anomalies of nose, face, skull and neck	1
Musculo. anomalies, thorax and neck	1
Anomalies of musculo. system	1
Anomalies of abdominal wall-hernia	2
Exomphalos	1
Anomalies of skin or integument	1
Endocrine & metabolic disorder	2
Other congenital anomalies	1
Total	71

TABLE 6
NUMBER OF BOYS AND GIRLS BORN FOLLOWING IVF AND DI TREATMENTS

	BOYS	GIRLS	TOTAL
DI	728 (51.7%)	680 (48.3%)	1408
IVF	1564 (51.6%)	1469 (48.4%)	3033

TABLE 7
IVF SUCCESS RATES BY NUMBER OF ATTEMPTS (ALL CENTRES)

NO OF ATTEMPTS	PATIENTS TREATED	CLINICAL PREGNANCY RATES % Per Treatment Cycle	LIVE BIRTH RATES % Per Treatment Cycle
1	6952	18.3	14.0
2	4206	16.8	12.5
3	2260	16.9	13.0
4	1260	14.7	10.5
5	663	12.9	9.2
6	338	13.4	9.0
7	199	10.8	7.5
8	137	12.3	6.8
9	96	14.0	9.0
10	60	13.4	10.4
11	36	8.3	2.8
12	24	4.2	4.2
13	11	7.6	0.0
14	6	0.0	0.0
15	6	33.3	16.6

TABLE 8
DI SUCCESS RATES BY NUMBER OF ATTEMPTS (ALL CENTRES)

NO OF ATTEMPTS	PATIENTS TREATED	CLINICAL PREGNANCY RATES % Per Treatment Cycle	LIVE BIRTH RATES % Per Treatment Cycle
1	3217	18.8	16.6
2	2943	8.9	7.0
3	2547	7.0	5.2
4	2249	5.9	4.3
5	2076	7.0	5.1
6	1815	6.0	4.7
7	1436	5.9	4.4
8	1256	6.2	4.4
9	1101	6.0	4.6
10	871	5.0	3.9
11	767	6.2	5.3
12	656	6.8	5.2
13	518	4.9	2.8
14	453	5.6	3.9
15	365	4.3	2.9

ANNEX 8:

GLOSSARY OF TERMS

TERM	DEFINITION
Cervical Mucus Defects	The secretions from the cervical canal may prevent sperm from entering the uterus
Clinical Pregnancy	Ultrasound evidence of a fetal heart
Donor Insemination (DI)	The insemination into a woman of donor sperm (at the cervical opening or into the cervical canal)
Ectopic Pregnancy	Pregnancy (sac) outside the uterus
Egg Collections	Successful egg collection procedure
Embryo Transfer	Transfer of one or more embryos to the uterus
Endometriosis	Endometrial cells, which normally line the uterus, implant around the outside of the uterus and/or ovaries
Female Factor	This term covers any reason why a woman is infertile, such as ovulation failure or damage to the fallopian tubes
Gamete	The male sperm or the female egg
GIFT	Gamete Intra-fallopian Transfer. Sperm and a maximum of three eggs are transferred together to one or both of a woman's fallopian tube(s). GIFT is a fertility treatment only licensed by the Authority if donor gametes are used
In Vitro Fertilisation (IVF)	Sperm and eggs are collected and put together to achieve fertilisation outside the body. Up to three of the resulting embryos can be transferred into a woman's uterus at one time
Intrauterine Insemination (IUI)	The insemination into a woman of specially prepared sperm through the cervical canal into the uterine cavity
Live Birth	The delivery of one or more babies
Male Factor	This term covers any reason why the male partner's sperm may be less effective or incapable of fertilisation, ranging from a failed reversal of a vasectomy to the absence of viable sperm

Miscarriage	Spontaneous complete loss of a pregnancy before 24 weeks
Miscarriage Rate	Proportion of pregnancies which miscarry
Multiple Birth	Birth of more than one baby from a pregnancy (these are counted as single live births irrespective of the number of babies)
Multiple Birth Rate	This rate is calculated as a proportion of all multiple births
Multiple Clinical Pregnancy	Presence of two or more fetal hearts in a clinical pregnancy
Multiple Clinical Pregnancy Rate	This rate is calculated as a proportion of all multiple clinical pregnancies
Perinatal Death	The death of a baby either in the uterus after 24 weeks pregnancy (stillbirth) or within one week after live birth
Superovulation	The stimulation of a woman's ovaries with drugs to produce more eggs than usual in a monthly cycle
Termination of Pregnancy	Induced loss of a complete clinical pregnancy
Treatment Cycle	a) IVF with fresh embryos: a cycle begins with the administration of drugs for the purpose of superovulation, or if no drugs are used, with the attempt to collect eggs b) IVF with frozen-thawed embryos: a cycle begins with the removal of the stored embryos in order to be thawed and then transferred For DI a treatment cycle begins when the first insemination with donor sperm takes place
Unknown Outcome	The outcome of a clinical pregnancy is unknown due to incomplete information being returned by a centre
Unstimulated ("natural")	No drugs were given to stimulate the cycle (see Superovulation)
Uterine Fibroids	Benign growths of fibrous connective tissue and muscle that develop within the uterine wall and sometimes interfere with the implantation of an embryo